Medicare Program Integrity Manual
Chapter 15 - Medicare Enrollment

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15.1 – Introduction to Provider Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10))

This chapter specifies the resources and procedures Medicare fee-for-service contractors must use to establish and maintain provider and supplier enrollment in the Medicare program. These procedures apply to carriers, fiscal intermediaries, Medicare administrative contractors and the National Supplier Clearinghouse (NSC), unless contract specifications state otherwise.

No provider or supplier shall receive payment for services furnished to a Medicare beneficiary unless the provider or supplier is enrolled in the Medicare program. Further, it is essential that each provider and supplier enroll with the appropriate Medicare fee-for-service contractor.

15.1.1 – Definitions

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Below is a list of terms commonly used in the Medicare enrollment process:

Accredited provider/supplier means a supplier that has been accredited by a CMS-designated accreditation organization.

Advanced diagnostic imaging service means any of the following diagnostic services:

(i) Magnetic Resonance Imaging (MRI).
(ii) Computed Tomography (CT).
(iii) Nuclear Medicine.
(iv) Positron Emission Tomography (PET).

Applicant means the individual (practitioner/supplier) or organization who is seeking enrollment into the Medicare program.

Approve/Approval means the enrolling provider or supplier has been determined to be eligible under Medicare rules and regulations to receive a Medicare billing number and be granted Medicare billing privileges.

Authorized Official means an appointed official (e.g., chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

Billing Agency means a company that the applicant contracts with to prepare, edit and/or submit claims on its behalf.

Change of Ownership (CHOW) is defined in 42 CFR §489.18 (a) and generally means, in the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law. In the case of a corporation, the term generally means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

CMS-approved accreditation organization means an accreditation organization designated by CMS to perform the accreditation functions specified.

Deactivate means that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

Delegated Official means an individual who is delegated by the "Authorized Official," the authority to report changes and updates to the enrollment record. The delegated official must be an individual with an ownership or control interest in (as that term is defined in section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the provider or supplier.

Deny/Denial means the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges.

Enroll/Enrollment means the process that Medicare uses to grant Medicare billing privileges.

Enrollment Application means a paper CMS-855 enrollment application or the equivalent electronic enrollment process approved by the Office of Management and Budget (OMB).

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges;

(ii) Suspension or revocation of a license to provide health care by any State licensing authority;

(iii) Revocation or suspension by an accreditation organization;

(iv) A conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(v) An exclusion or debarment from participation in a Federal or State health care program.

Legal Business Name is the name that is reported to the Internal Revenue Service (IRS).

Managing Employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier.

(For Part A providers, the Medicare Identification Number (MIN) is the CMS Certification Number (CCN). For Part B suppliers other than suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), the MIN is the Provider Identification Number (PIN). For DMEPOS suppliers, the MIN is the number issued to the supplier by the NSC)**.**

National Provider Identifier is the standard unique health identifier for health care providers (including Medicare suppliers) and is assigned by the National Plan and Provider Enumeration System (NPPES).

Operational means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims; and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) to furnish these items or services.

Owner means any individual or entity that has any partnership interest in, or that has 5 percent or more direct or indirect ownership of, the provider or supplier as defined in sections 1124 and 1124(A) of the Social Security Act.

Physician or non-physician practitioner organization means any physician or non-physician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

Prospective Provider means any entity specified in the definition of "provider" in 42 CFR §498.2 that seeks to be approved for coverage of its services by Medicare.

Prospective Supplier means any entity specified in the definition of "supplier" in 42 CFR §405.802 that seeks to be approved for coverage of its services under Medicare.

Provider is defined at 42 CFR §400.202 and generally means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice, that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Reassignment means that an individual physician or non-physician practitioner, except physician assistants, has granted a clinic or group practice the right to receive payment for the practitioner's services.

Reject/Rejected means that the provider or supplier's enrollment application was not processed due to incomplete information or that additional information or corrected information was not received from the provider or supplier in a timely manner.

Revoke/Revocation means that the provider or supplier's billing privileges are terminated.

Supplier is defined in 42 CFR §400.202 and means a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare.

Tax Identification Number means the number (either the Social Security Number (SSN) or Employer Identification Number (EIN)) the individual or organization uses to report tax information to the IRS.

15.1.2 – Medicare Enrollment Application (CMS-855)

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Providers and suppliers, including physicians may enroll or update their Medicare enrollment record using the:

- Internet-based Provider Enrollment, Chain and Ownership System (PECOS), or

- Paper enrollment application process (e.g., CMS-855I).

The Medicare enrollment applications are issued by CMS and approved by OMB. (When available, the forms can be accessed through the Provider Enrollment, Chain and Ownership System's (PECOS) Web-based enrollment process, which is based off of the information collected on the CMS-855 forms).

The five forms are distinguished as follows:

- CMS-855I - This form should be completed by individual practitioners, including physicians and non-physician practitioners, who render Medicare Part B services to Medicare beneficiaries. (This includes a physician or practitioner who: (1) is the sole owner of a professional corporation, professional association, or limited liability company, and (2) will bill Medicare through this business entity)**.**

- CMS-855R - An individual who renders Medicare Part B services and seeks to reassign his or her benefits to an eligible entity should complete this form for each entity eligible to receive reassigned benefits. The person must be enrolled in the Medicare program as an individual prior to reassigning his or her benefits.

- CMS-855B - This application should be completed by a supplier organization (e.g., ambulance company) that will bill Medicare for Part B services furnished to Medicare beneficiaries. It is not used to enroll individuals.

- CMS-855A - This application should be completed by institutional providers (e.g., hospital) that will furnish Medicare Part A services to Medicare beneficiaries.

- CMS-855S – This application should be completed by DMEPOS suppliers. The NSC is responsible for processing this type of enrollment application.

A separate application must be submitted for each provider/supplier type.
When a prospective provider or supplier contacts the contractor to obtain a paper enrollment CMS-855 application, the contractor shall furnish:

- Encourage a provider or supplier to submit the enrollment application using Internet-based PECOS.

- The CMS Web site at which the applications can be accessed (www.cms.hhs.gov/MedicareProviderSupEnroll);

- Notification of any supporting documentation required for the applicant's provider/supplier type;

- The Electronic Funds Transfer Authorization Agreement (CMS-588) (Note: The NSC is only required to collect the CMS-588 with initial enrollment applications);

- The Electronic Data Interchange (EDI) agreement (Note: This does not apply to the NSC);

- The Medicare Participating Physician or Supplier Agreement (CMS-460), with an explanation of the purpose of the agreement and how it differs from the actual enrollment process. (This only applies to carriers.)

- The contractor's address, so that the applicant knows where to return the completed application;

- If the applicant is a certified supplier or provider, notification that the applicant should contact the State agency for any state-specific forms and to begin preparations for a State survey. (This does not apply for those certified entities, such as FQHCs, that do not receive a State survey.) The notification can be given in any manner the contractor chooses.

15.1.3 – Medicare Contractor Duties

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The contractor must adhere to the processing guidelines established in this chapter 15

(hereinafter generally referred to as "this manual"). In addition, the contractor shall assign the appropriate number of staff to the Medicare enrollment function to meet established processing timeframes.

The contractor shall provide training to new employees and provide refresher training, as necessary, to existing employees to ensure that each employee processes enrollment applications in a timely, consistent, and accurate manner. Training shall include, at a minimum:

- An overview of the Medicare program;

- A review of applicable regulations, manual instructions and other guidance issued by CMS;

- A review of the contractor's enrollment processes and procedures; and

- Training regarding the Provider Enrollment, Chain and Ownership System (PECOS).

- For new employees, the contractor shall also:

- Provide side-by-side training with an experienced provider enrollment analyst;

- Test the new employee to ensure that the analyst understands Medicare enrollment policy and contractor processing procedures, including the use of PECOS; and

- Conduct end-of-line quality reviews for 6 months after training or until the analyst demonstrates a clear understanding of Medicare enrollment policy and contractor procedures.

- Contractors shall process all enrollment actions (i.e., initials, changes, revalidations and reactivations) through PECOS.

- Contractors shall deactivate or revoke in MCS and FISS only if the provider or supplier is not in PECOS.

- Contractors shall close or delete any aged logging and trackings (L&Ts) that exceed 120 days for which there is not an associated enrollment application.

- Contractors shall participate in UAT testing for each PECOS release.

- When requested, contractors shall attend scheduled PECOS training.

- Contractors shall report PECOS validation and production processing problems through the designated tracking system for each system release.

Moreover, each contractor shall develop (and update as needed) a written training guide for new and current employees on the proper processing of CMS-855 applications as well as the appropriate entrance of data into PECOS.

Conduct Prescreening

- Review the application to determine that it is complete and that all information and supporting documentation required for the applicant's provider/supplier type has been submitted on and with the appropriate enrollment application.

Conduct Verification, Validation, and Final Processing

- Verify and validate the information collected on the enrollment application (see section 7, of chapter 15 for additional information).

- Coordinate with State survey/certification agencies and regional offices (ROs), as needed

- Collect and maintain the application's certification statement (in house) to verify and validate Electronic Funds Transfer (EFT) changes. The change request signature must be checked against the original signature to determine the validity of any change to EFT information. This check can be made against a digital/photo image kept in-house.

- Confirm that the applicant, all individuals and entities listed on the application, and any names or entities ascertained through the use of an independent verification source, are not presently excluded from the Medicare program by the HHS Office of the Inspector General (OIG). Contractors shall verify eligibility using the Medicare Exclusion Database (MED), and the General Services Excluded Parties List System.

15.2 – Provider and Supplier Business Structure

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10))

This section explains the legalities of various types of business organizations that may enroll, including sole proprietorships. Note that the provider's organizational structure can have a significant impact on the type of information it must furnish on the CMS-855.

Business organizations are generally governed by State law. Thus, State X may have slightly different rules than State Y regarding certain entities. (In fact, X may permit the creation of certain types of legal entities that Y does not.) The discussion below gives only a broad overview of the principal types of business entities and does not take into account different State nuances.

Since CMS issues a 1099 based on an enrolled entity's business structure, providers and

suppliers should consult with their accountant or legal advisor to ensure that they are establishing the correct business structure.

A. Sole Proprietorships

A business is a sole proprietorship if it meets all of the following criteria:

- It files a Schedule C (1040) with the IRS (this form reports the business's profits/losses);
- One person owns all of the business's assets; and
- It is not incorporated.

A sole proprietorship is not a corporation. Suppose a physician operates his/her business as a home health agency. If he/she incorporates his/her business, the business becomes a corporation (even though the physician is the only stockholder). Thus, the frequently-used term "unincorporated sole proprietorship" is a misnomer, because sole proprietorships by definition are unincorporated. In addition, merely because the sole proprietor hires employees does not mean that the business is no longer a sole proprietorship. Assume W is a sole proprietor and he hires X, Y, and Z as employees. W's business is still a sole proprietorship because he remains the 100% owner of the business. On the other hand, if W had sold parts of his sole proprietorship to X, Y, and Z the business would no longer be a sole proprietorship, as there is now more than one owner.

Note that professional associations (PAs) are generally not considered to be sole proprietorships; the PA designation is typically used in States that do not allow individuals to incorporate and form professional corporations. The PA will have its own EIN and is considered, like a professional corporation, to be a legal entity that is separate and distinct from the individual.

B. Partnerships

A partnership is an association of two or more persons/entities who carry on a business for profit. Each partner in a partnership is an owner. If A and B form the "Y Partnership" and each contributes $50,000 to start up the business, each partner owns one-half of Y.

In several respects, a partnership is the opposite of a corporation:

- Each partner is liable for all the debts of the partnership. Using the example above, suppose the Y Partnership breached a contract it had with Mr. X, who now sues for $10,000. Since each partner is liable for all debts, X can collect the entire $10,000 from A, or from B, or $5,000 from each, etc. This is because, unlike a corporation, a partnership is not really a separate and distinct entity from its partners/owners; the partners are the partnership. If Y had been a corporation, the owners (A and B) would likely have been be shielded from liability.

- There is no "double taxation" with partnerships. The partnership itself does not pay taxes, although each partner pays taxes on any income he/she earns from the business.

- Unlike a corporation, a partnership generally does not file papers with the State upon its creation (i.e., it does not file the equivalent of articles of incorporation). Instead, a partnership has a "partnership agreement," which amounts to a contract between the partners outlining duties, responsibilities, powers, etc.

- Each partner has the right to participate in running the business's day-to-day operations, unless the partnership agreement dictates otherwise.

An alternative type of partnership is a limited partnership (as opposed to a "general partnership," described above). While possessing many of the characteristics of a general partnership, there are some key differences. First, a limited partnership (LP) must file formal documents with the State. Second, a LP has two types of partners – general and limited. The general partner(s) runs the business, yet is personally responsible for all of the LP's debts. Conversely, the limited partner(s) have limited liability yet cannot participate in the management of the business.

C. Limited Liability Companies (LLC)

A limited liability company (LLC) is a legal entity that is neither a partnership nor a corporation, but has characteristics of both. Its owners have limited liability (just like stockholders in a corporation). In addition, the LLC does not pay Federal taxes (similar to a partnership), although its owners – usually referred to as "members" - must pay taxes on any dividends they reap. An LLC thus contains the best attributes of corporations and partnerships, which is why LLCs are rapidly gaining in popularity.

An LLC should not be confused with a limited liability <u>corporation</u>, which is a type of corporation in some States. A limited liability <u>company</u> is <u>not</u> a corporation or partnership, but a distinct legal entity created and regulated by special State statutes.

Note that certain CMS-855 information is required of different entities. The primary example of this is in section 6 (Managing Individuals). If the provider is a corporation, it must list its officers and directors on the form. Partnerships and LLCs, on the other hand, do not have officers or directors and thus need not list them.

D. Joint Ventures

A joint venture is when two or more persons/entities combine efforts in a business enterprise and agree to share profits and losses. It is very similar to a partnership, and is treated as a partnership for tax purposes. The key difference is that a partnership is an ongoing business, while a joint venture is a <u>temporary</u>, one-time business undertaking. A joint venture, therefore, can be classified as a "temporary partnership."

E. Corporations

A corporation is an entity separate and distinct from its owners (called stockholders, or shareholders). To form a corporation, various documents – such as articles of incorporation – must be filed with the State in which the business will incorporate. The key elements of a corporation are:

- Limited Liability – This is the main reason why a business chooses to operate as a corporation. Suppose Corporation X has ten stockholders, each owning 10% of the business. X breached a contract it had with Company Y, and now Y wants to sue X's owners. Unfortunately for Y, it can really only sue X itself; it cannot go after X's shareholders. The corporation's owners are essentially shielded from liability for the actions of the corporation because, as stated above, a corporation is separate and distinct from its owners.

Despite the concept of limited liability, there may be instances where a corporation's owners/stockholders can be held personally liable for the corporation's debts. This is known as "piercing the corporate veil" (PCV), whereby one tries to get past the brick wall of the corporation in order to collect money from the owners behind that wall. However, PCV is a difficult thing to do and many courts are unwilling to allow it, meaning that plaintiffs can only collect from the corporation itself.

- "Double" Taxation – This is the principal reason why a business chooses not to be a corporation. "Double" taxation means that: (1) the corporation itself must pay taxes, AND (2) each shareholder must pay taxes on any dividends he/she receives from the business.

- Board of Directors – Most corporations are run by a governing body, typically called a Board of Directors.

Two special types of corporations contractors may encounter are:

- "Professional Corporation" or "PC." In general, a PC: (1) is organized for the sole purpose of rendering professional services (such as medical or legal), and (2) all stockholders in the PC must be licensed to render such services. Thus, if A, B and C want to form a physician practice (each is a 1/3 stockholder) and only A is a medical professional, the PC probably cannot be formed (depending, of course, on what the applicable State PC statute says). In addition, the title of a PC will usually end in "PC," "PA" (Professional Association) or "Chartered."

- "Close" Corporation (or "closely-held" corporation) – This is a type of corporation with a very limited number of stockholders. Unlike a "regular" corporation, the entity's board of directors generally does not run the business; rather, the shareholders do. The stock is typically not sold to outsiders.

Although PCs and CCs are considered "corporations" for enrollment purposes, State laws governing these entities are often different from those that govern "regular" corporations (i.e., States have separate statutes for "regular" corporations and for PCs/CCs.) In many cases, an entity must specifically elect to be a PC or CC when filing its paperwork with the State.

F. Non-Profit Organizations

The term "non-profit organization" is misleading. It is not an organization that is forbidden to make a profit. Rather, it means that all of the organization's profits are put back into the entity to promote its goals, which are usually political, social, religious, or charitable in nature. In other words, the NPO is not organized primarily for profit, but instead to further some other goal. An entity can acquire NPO status by obtaining a 501(c)(3) certification from the IRS (meaning it is tax-exempt) or by acquiring such status from the State it is located in.

The NPO status is important for enrollment purposes because NPOs generally do not have owners. Thus, a NPO need not list any owners in sections 5 or 6 of the CMS-855.

G. Government-Owned Entities

For purposes of enrollment, a government-owned entity (GOE) exists when a particular government body (e.g., Federal, State, city or county agency) will be legally and financially responsible for Medicare payments received. For example, suppose Smith County operates Hospital X. Medicare overpaid X $100,000 last year. If Smith County is the party responsible for reimbursing Medicare this amount, X is considered a government-owned entity.

Note that:

- GOEs do not have "owners." Thus, section 5 of the CMS 855 need only contain the name of the government body in question. Using our example above, this would be Smith County.

- For section 6 (Managing Individuals), the only people that must be listed are "managing employees." This is because GOEs do not have corporate officers or directors.

The entity must submit a letter from the government body certifying that the government will be responsible for any Medicare payments.

15.3 – National Provider Identifier (NPI)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Submission of NPI

Every provider that submits an enrollment application must furnish its NPI(s) in the applicable section(s) of the CMS-855. The provider need not submit a copy of the NPI notification it received from the National Plan and Provider Enumeration System (NPPES) unless requested to do so by the contractor. Similarly, if the provider obtained its NPI via the Electronic File Interchange (EFI) mechanism, the provider need not submit a copy of the notification it received from its EFI Organization (EFIO) unless requested to do so by the contractor. (The notification from the EFIO will be in the form of a letter or e-mail.) If paper documentation of a provider's NPI is requested by the contractor, the latter may accept a copy of the provider's NPI Registry's Details Page in lieu of a copy of the NPI notification. The Details Page contains more information than is contained on the NPI notification, and providers may be able to furnish NPI Registry Details Pages more quickly than copies of their NPI notifications.

The aforementioned requirement to list all applicable NPIs on the CMS-855 applies to all applications. (The only exceptions to this involve voluntary terminations, deactivations, deceased providers, and CHOW applications submitted by the old owner. NPIs are not required in these instances.) Thus, for instance, if a reassignment package is implicated, the NPIs for all involved individuals and entities must be furnished; even if an individual is reassigning benefits to an enrolled group, the group's NPI must be furnished on the CMS-855R.

NOTE: The NSC shall obtain the NPPES notification from the applicant or verify the NPI and the Type of NPI (i.e., Type 1 or Type 2) through the NPI Registry.

B. Additional NPI Information

If a provider submits an NPI notice to the contractor as a stand-alone document (i.e., no CMS 855 was submitted), the contractor shall not create an L & T record in PECOS for the purpose of entering the NPI. The contractor shall simply place the notice in the provider file. Contractors shall only enter NPI data into PECOS that is submitted in conjunction with a CMS 855 (e.g., initial, change request). Thus, if a provider submits a CMS 855 change of information that only reports the provider's newly assigned NPI, or reports multiple NPIs that need to be associated with a single Medicare identification number, the contractor may treat this as a change request and enter the data into PECOS.

C. Subparts - General

The contractor shall review and become familiar with the principles outlined in the "Medicare Expectations Subpart Paper," the text of which follows below:

The CMS encourages all providers to obtain NPIs in a manner similar to how they receive OSCAR numbers (i.e., a "one-to-one relationship"). For instance, suppose a home health agency is enrolling in Medicare. It has a branch as a practice location. The main provider and the branch will typically receive separate (albeit very similar) OSCAR numbers. It would be advisable for the provider to obtain an NPI for the main

provider and another one for the branch – that is, one NPI for each OSCAR number.

Further instructions on how contractors shall deal with NPI-related matters will be issued in the near future.

D. Medicare Subparts Paper - Text

MEDICARE EXPECTATIONS ON DETERMINATION OF SUBPARTS BY MEDICARE ORGANIZATION HEALTH CARE PROVIDERS WHO ARE COVERED ENTITIES UNDER HIPAA

January 2006

Purpose of this Paper

Medicare assigns unique identification numbers to its enrolled health care providers that are used to identify the enrolled health care providers in the HIPAA standard transactions that they conduct with Medicare (such as electronic claims, remittance advices, eligibility inquiries/responses, claim status inquiries/responses, and coordination of benefits) and in cost reports and other non-standard transactions.

This paper is a reference for Medicare carriers and fiscal intermediaries (FIs). It reflects the Medicare program's expectations on how its enrolled organization health care providers who are covered entities under HIPAA1 will determine subparts and obtain NPIs for themselves and any subparts. These expectations may change over time to correspond with any changes in Medicare statutes, regulations, or policies that affect Medicare provider enrollment.

These expectations are based on the NPI Final Rule, on statutory and regulatory requirements with which Medicare must comply, and on policies that are documented in Medicare operating manuals but have not yet been codified. These Medicare statutes, regulations and policies pertain to conditions for provider participation in Medicare, enrollment of health care providers in Medicare and assignment of identification numbers for billing and other purposes, submission of cost reports, calculation of payment amounts, and the reimbursement to enrolled providers for services furnished to Medicare beneficiaries.

This paper categorizes Medicare's enrolled organization health care providers as follows:

- Certified providers and suppliers

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1 Covered entities under HIPAA are health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a health transaction for which the Secretary of HHS has adopted a standard (referred to in this paper as HIPAA standard transactions). Most Medicare Organization health care providers send electronic claims to Medicare (they are HIPAA standard transactions), making them covered health care providers (covered entities).

- Supplier groups and supplier organizations
- Suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS)

This paper is not intended to serve as official HHS guidance to the industry in determining subparts for any covered health care providers other than those who are organizations and are enrolled in the Medicare program. This paper does not address health care providers who are enrolled in Medicare as individual practitioners. These practitioners are Individuals (such as physicians, physician assistants, nurse practitioners, and others, including health care providers who are sole proprietors). In terms of NPI assignment, an Individual is an Entity Type 1 (Individual) and is eligible for a single NPI. As Individuals, these health care providers cannot be subparts and cannot designate subparts. A sole proprietorship is a form of business in which one person owns all of the assets of the business and the sole proprietor is solely liable for all of the debts of the business. There is no difference between a sole proprietor and a sole proprietorship. In terms of NPI assignment, a sole proprietor/sole proprietorship is an Entity Type 1 (Individual) and is eligible for a single NPI. As an Individual, a sole proprietor/sole proprietorship cannot have subparts and cannot designate subparts.

Discussion of Subparts in the NPI Final Rule and its Applicability to Enrolled Medicare Organization Health Care Providers

The NPI Final Rule adopted the National Provider Identifier (NPI) as the standard unique health identifier for health care providers for use in HIPAA standard transactions. On or before May 23, 2007, all HIPAA covered entities (except small health plans), to include enrolled Medicare providers and suppliers that are covered entities, must obtain NPIs and must use their NPIs to identify themselves as "health care providers" in the HIPAA standard transactions that they conduct with Medicare and other covered entities. Covered organization health care providers are responsible for determining if they have "subparts" that need to have NPIs. If such subparts exist, the covered organization health care provider must ensure that the subparts obtain their own unique NPIs, or they must obtain them for them.

The NPI Final Rule contains guidance for covered organization health care providers in determining subparts. Subpart determination is necessary to ensure that entities within a covered organization health care provider that need to be uniquely identified in HIPAA standard transactions obtain NPIs for that purpose.

The following statements apply to **all** entities that could be considered subparts:

- A subpart is not itself a separate legal entity, but is a part of a covered organization health care provider that is a legal entity. (All covered entities under HIPAA are legal entities.)

- A subpart furnishes health care as defined at 45 CFR 160.103.

The following statements may relate to some or all of the entities that a Medicare covered organization health care provider could consider as subparts:

- A subpart may or may not be located at the same location as the covered organization health care provider of which it is a part.

- A subpart may or may not have a Taxonomy (Medicare specialty) that is the same as the covered organization health care provider of which it is a part.

- Federal statutes or regulations pertaining to requirements for the unique identification of enrolled Medicare providers may relate to entities that could be considered subparts according to the discussion in the NPI Final Rule. Medicare covered organization health care providers must take any such statutes or regulations into account to ensure that, if Medicare providers are uniquely identified now by using Medicare identifiers in HIPAA standard transactions, they obtain NPIs in order to ensure they can continue to be uniquely identified. Medicare is transitioning from the provider identifiers it currently uses in HIPAA standard transactions (for organizations, these could be OSCAR Numbers, PINs, or NSC Numbers—known as legacy identifiers or legacy numbers) to NPIs. This makes it necessary that Medicare organization health care providers obtain NPIs because the NPIs will replace the identifiers currently in use in standard transactions with Medicare and with all other health plans. In addition, Medicare organization health care providers must determine if they have subparts that need to be uniquely identified for Medicare purposes (for example, in HIPAA standard transactions conducted with Medicare). If that is the case, the subparts will need to have their own unique NPIs so that they can continue to be uniquely identified in those transactions.

- A subpart that conducts any of the HIPAA standard transactions separately from the covered organization health care provider of which it is a part must have its own unique NPI.

Enrolled Medicare organization health care providers who are covered entities under HIPAA must apply for NPIs as Organizations (Entity Type 2). Organization health care providers as discussed in this paper are corporations or partnerships or other types of businesses that are considered separate from an individual by the State in which they exist. Subparts of such organization health care providers who apply for NPIs are also Organizations (Entity Type 2).

Medicare Statutes, Regulations, Manuals

The Social Security Act (sections 1814, 1815, 1819, 1834, 1861, 1865, 1866, and 1891) and Federal regulations (including those at 42 CFR 400.202, 400.203, 403.720, 405.2100, 409.100, 410.2, 412.20, 416.1, 418.1, 424, 482.1, 482.60, 482.66, 483, 484, 485, 486, 489, 491, and 493.12) establish, among other things, the Conditions for

2 Clinical laboratory certification is handled by the Food and Drug Administration.

Participation for Medicare providers and set requirements by which Medicare enrolls providers, requires cost reports, calculates reimbursement, and makes payments to its providers. These Medicare statutory and regulatory requirements are further clarified in various Medicare operating manuals, such as the State Operations Manual and the Program Integrity Manual, in which requirements and policies concerning the assignment of unique identification numbers, for billing and other purposes, are stated.

Medicare Organization Providers and Subparts: Certified Providers and Suppliers

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to Medicare certified providers and suppliers for billing purposes.

Certified Providers that bill Medicare fiscal intermediaries (hereinafter referred to as "providers"):

- Providers apply for Medicare enrollment by completing a CMS-855A.
- Most providers are surveyed and certified by the States3 prior to being approved as Medicare providers.
- Providers have in effect an agreement to participate in Medicare.4
- Providers include, but are not limited to: skilled nursing facilities, hospitals5, critical access hospitals, home health agencies, rehabilitation agencies (outpatient physical therapy, speech therapy), comprehensive outpatient rehabilitation facilities, hospices, community mental health centers, religious non-medical health care institutions.
- Providers are assigned OSCAR numbers to use to identify themselves in Medicare claims and other transactions, including cost reports for those providers that are required to file Medicare cost reports.
- In general, each entity that is surveyed and certified by a State is separately enrolled in Medicare and is considered a Medicare provider. (An exception involves home health agency branches. The branches are not separately enrolled Medicare providers.) In many cases, the enrolled provider is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

Certified Suppliers, most of which bill Medicare carriers:

- Certified suppliers apply for Medicare enrollment by completing a CMS-855B.
- Certified suppliers include ambulatory surgical centers, portable x-ray suppliers, independent clinical labs (CLIA labs), rural health centers, and federally qualified health centers.

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3 Religious non-medical health care institutions are handled differently.
4 Community mental health centers attest to such an agreement. Religious non-medical health care institutions are handled differently.
5 Hospitals bill carriers for certain types of services.

- Most certified suppliers bill the carriers; however, rural health centers and federally qualified health centers bill the fiscal intermediaries.
- Certified suppliers are typically surveyed and certified by the States prior to being approved for enrollment as Medicare certified suppliers. (For CLIA labs, each practice location at which lab tests are performed must obtain a separate CLIA Certificate for that location, though there are a few exceptions to this.)
- Certified suppliers may have in effect an agreement to participate in Medicare.
- Certified suppliers are assigned OSCAR numbers for purposes of identification within Medicare processes. However, the carriers assign unique identification numbers to certified suppliers for billing purposes. (For CLIA labs, a CLIA Number is typically assigned to each practice location for which a CLIA certificate is issued. A CLIA Number may not be used to identify a clinical laboratory as a "health care provider" in HIPAA standard transactions. The CLIA Number has no relation to the Medicare billing number.)

- In many cases, the enrolled certified supplier is not itself a separate legal entity; i.e., it is an entity that is a part of an enrolled provider or certified supplier that is a legal entity and is, for purposes of the NPI Final Rule, considered to be a subpart.

In general, Medicare bases its enrollment of providers and certified suppliers on two main factors: (1) whether a separate State certification or survey is required, and (2) whether a separate provider or certified supplier agreement is needed. (The Taxpayer Identification Number, or TIN, is a consideration as well, though not to the degree of the two main factors.) The CMS regional offices generally make the final determinations on both of these factors; hence, Medicare provider and certified supplier enrollment policy is dictated to a significant degree by the CMS regional offices' decisions in particular cases.

Medicare Expectations for NPI Assignments for Providers and Certified Suppliers: To help ensure that Medicare providers and certified suppliers do not experience denials of claims or delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled providers and certified suppliers to obtain its own unique NPI. These NPIs will eventually replace the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror Medicare enrollment, each enrolled provider and certified supplier that is a covered organization health care provider would ensure the following:

- Obtain its own unique NPI.

- Determine if it has any subparts that are themselves enrolled Medicare providers. If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them. Example: An enrolled provider (a hospital) owns 10 home health agencies, all operating under the TIN of the hospital. Because the hospital and each of the 10 home health agencies is separately surveyed and enters into its own

provider agreement with Medicare, a total of 11 unique NPIs should be obtained: one by the hospital, and one by each of the 10 home health agencies.

Regardless of how an enrolled provider or certified supplier that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if they exist), Medicare payments, by law, may be made only to an enrolled provider or certified supplier.

Medicare Organization Providers and Subparts: Supplier Groups and Supplier Organizations

Existing Medicare laws and regulations do not establish requirements concerning the assignment of unique identification numbers to supplier groups and supplier organizations for billing purposes.

- Supplier groups and supplier organizations apply for Medicare enrollment by completing a CMS-855B.
- Supplier groups and supplier organizations bill Medicare Part B carriers.
- Supplier organizations are certified by the States, or certified by the Food and Drug Administration (FDA), or must undergo an on-site inspection by the carrier. These requirements vary by type of supplier organization.
- Supplier groups are primarily group practices, such as a group of physicians or other practitioners.
- Supplier organizations include ambulance companies, mammography facilities, and independent diagnostic testing facilities (IDTFs).

Medicare enrolls supplier groups/supplier organizations based on Taxpayer Identification Numbers (TINs); that is, although a supplier group or supplier organization may have multiple locations, if each location operates under the same single TIN, Medicare does not separately enroll each location. There are exceptions:

1. When there is more than one Medicare specialty code associated with a single TIN. For instance, if a physician group practice is also an IDTF, it has two different Medicare specialties. The supplier group (the physician group practice) must enroll as a group and the supplier organization (the IDTF) must enroll as a supplier organization. The group practice would complete a CMS-855B and the IDTF would complete a CMS-855B. Each one would receive its own unique Medicare billing number.

2. If a separate site visit, State certification, or on-site inspection by the carrier or if FDA certification is required for each practice location of that supplier group/supplier organization.

In those above exceptions, Medicare separately enrolls each different Medicare specialty and each separately visited, certified or carrier-inspected practice location.

Medicare Expectations for NPI Assignments for Supplier Groups and Supplier Organizations: To help ensure that Medicare supplier groups and supplier organizations do not experience delays in Medicare claims processing or reimbursement, Medicare encourages each of its enrolled supplier groups and supplier organizations to obtain its own unique NPI. These NPIs will eventually replace the legacy numbers that are used today in HIPAA standard transactions and in other transactions, such as cost reports. In order for subpart determinations to mirror Medicare enrollment, each enrolled supplier group and supplier organization that is a covered organization health care provider would ensure the following:

- Obtain its own unique NPI.
- Determine if it has any subparts that are themselves enrolled Medicare providers.

If there are subparts, ensure that they obtain their own unique NPIs, or obtain the NPIs for them.

EXAMPLE: An enrolled IDTF has four different locations, and each one must be separately inspected by the carrier. All four locations operate under a single TIN. Because each location is separately inspected in order to enroll in Medicare, a total of four unique NPIs should be obtained: one for each location.

Regardless of how an enrolled supplier group or supplier organization that is a covered organization health care provider determines subparts (if any) and obtains NPIs (for itself or for any of its subparts, if they exist), Medicare payments, by law, may be made only to an enrolled supplier group or supplier organization.

Medicare Organization Providers and Subparts: Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, or Supplies (DMEPOS)

Medicare regulations require that each practice location of a supplier of DMEPOS (if it has more than one) must, by law, be separately enrolled in Medicare and have its own unique Medicare billing number.

- A supplier of DMEPOS enrolls in Medicare through the National Supplier Clearinghouse (NSC) by completing a CMS-855S.

- Suppliers of DMEPOS bill durable medical equipment regional carriers (DMERCs).

- Suppliers of DMEPOS include but are not limited to pharmacies, oxygen suppliers, and outpatient physical therapy agencies. (Any organization that sells equipment or supplies that are billed to Medicare through the DMERCs must be enrolled as a supplier of DMEPOS through the NSC. Sometimes, these are organizations who also furnish services that are covered by Medicare, such as

ambulatory surgical centers. In order to be reimbursed for the DME supplies that they sell, they must separately enroll in Medicare as a supplier of DME.)

Medicare Expectations for NPI Assignments for Suppliers of DMEPOS: Each enrolled supplier of DMEPOS that is a covered entity under HIPAA must designate each practice location (if it has more than one) as a subpart and ensure that each subpart obtains its own unique NPI.

Final Notes About NPIs

Enrolled organization health care providers or subparts who bill more than one Medicare contractor: An enrolled organization health care provider or subpart is expected to use a single (the same) NPI when billing more than one Medicare contractor. For example, a physician group practice billing a Maryland carrier and also billing a Pennsylvania carrier would use a single (the same) NPI to bill both carriers.

Enrolled organization health care providers or subparts who bill more than one type of Medicare contractor: Generally, the type of service being reported on a Medicare claim determines the type of Medicare contractor who processes the claim. Medicare will expect an enrolled organization health care provider or subpart to use a single (the same) NPI when billing more than one type (fiscal intermediary, carrier, RHHI, DMERC) of Medicare contractor. However, in certain situations, Medicare requires that the organization health care provider (or possibly even a subpart) enroll in Medicare as more than one type of provider. For example, an ambulatory surgical center enrolls in Medicare as a certified supplier and bills a carrier. If the ambulatory surgical center also sells durable medical equipment, it must also enroll in Medicare as a Supplier of DME and bill a DMERC. This ambulatory surgical center would obtain a single NPI and use it to bill the fiscal intermediary and the DMERC. Medicare expects that this ambulatory surgical center would report two different Taxonomies when it applies for its NPI: (1) that of ambulatory health care facility—clinic/center--ambulatory surgical (261QA1903X) and (2) that of suppliers—durable medical equipment & medical supplies (332B00000X) **or** the appropriate sub-specialization under the 332B00000X specialization.

Enrolled organization health care providers who determine subparts for reasons unrelated to Medicare statutes, regulations or policies:

Consistent with the NPI Final Rule, covered organization health care providers designate subparts for reasons that are not necessarily related to Medicare statutes or regulations. If a Medicare organization health care provider designates as subparts entities other than those who are enrolled Medicare providers, and those subparts obtain their own NPIs and use those NPIs to identify themselves in HIPAA standard transactions with Medicare, those NPIs will not identify enrolled Medicare providers.

Medicare is not required to enroll them. (NPI Final Rule, page 3441: "If an organization health care provider consists of subparts that are identified with their own unique NPIs, a health plan may decide to enroll none, one, or a limited number of them (and to use only the NPIs of the one(s) it enrolls."))

Medicare will, of course, use NPIs to identify health care providers and subparts in HIPAA standard transactions. (NPI Final Rule, page 3469: section 162.412(a): "A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.") Medicare will ensure that the NPIs it receives in HIPAA standard transactions are valid6. Medicare will reject HIPAA standard transactions that contain invalid NPIs. Valid NPIs, however, like the provider identifiers used today, must be "known" to Medicare. Medicare is not permitted to make payments for services rendered by non-Medicare providers7, nor is it permitted to reimburse providers who are not enrolled in the Medicare program. Medicare will return, with appropriate messages, any HIPAA standard transactions containing valid but unrecognizable NPIs.

15.4 – Provider and Supplier Types/Services
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors shall consult other Medicare manuals for more information on how these providers and suppliers bill Medicare, their conditions of coverage and conditions of participation, etc.

15.4.1 – Intermediary-Enrolled Providers and Suppliers
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.1.1 - Community Mental Health Centers (CMHCs)
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

A community mental health center (CMHC) is a facility that provides mental health services. A CMHC must perform certain **"core services."** These are:

1. **Outpatient services** (This includes services for (1) children, (2) the elderly, (3) persons who are chronically mentally ill, and (4) certain persons who have been discharged from a mental health facility for inpatient treatment.)

2. **24-hour**-a-day emergency psychiatric services

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6 The check-digit algorithm will determine the validity of an NPI. This is not the same as knowing the health care provider being identified by a particular NPI.

7 There may be exceptions for emergency or very unusual situations.

3. **Day treatment** or other **partial hospitalization (PH) services,** or psychosocial rehabilitation services; and

4. **Screening** for patients being considered for admission to State mental health facilities.

NOTE: Partial hospitalization is the only core service for which a CMHC can bill Medicare as a CMHC. Thus, while a facility must furnish certain "core" services in order to qualify as a CMHC, it can only get reimbursed for one of them – partial hospitalization. However, the facility may still be able to enroll with a Medicare carrier as a clinic if it does not perform partial hospitalization services.

In some instances, these core services can be furnished under arrangement. This generally means that the facility can arrange for another facility to perform the service if, among other things, CMS determines that the following conditions are met:

- The CMHC arranging for the service in question is authorized by State law to perform the service itself;

- The arranging CMHC accepts full legal responsibility for the service; and

- There is a written agreement between the two entities.

While the CMHC generally has the option to furnish services under arrangement, there is actually an instance where the facility must do so. If the CMHC is located in a State that prohibits CMHCs from furnishing screening services (service #4 above), it must contract with another entity to have the latter perform the services. Any such arrangement must be approved by the regional office (RO). (See Pub. 100-07, State Operations Manual (SOM), chapter 2, section 2250, for additional information of core services and arrangements.)

A CMHC must provide mental health services principally to individuals who reside in a defined geographic area (service area); that is, they must service a distinct and definable community. A CMHC (or CMHC site) that operates outside of this specific community must – unless the RO holds otherwise - have a separate provider agreement/number and enrollment, and must individually meet all Medicare requirements.

B. Enrollment and Certification

Once it is determined whether the CMHC complies with Federal, State, and local laws, the RO will either approve or deny the CMHC's enrollment. This is the same process that virtually all certified providers and certified suppliers follow. Unlike most such entities, however, CMHCs are not surveyed by the State agency to determine the CMHC's compliance with Medicare laws (although the State may do a survey to verify compliance with State laws). Instead, the RO (or CMS-contracted personnel) will perform a site visit. The RO will not approve the CMHC unless the latter demonstrates

that it is furnishing the core services to a sufficient number of patients. In addition, CMS reserves the right to request at any time documentation from the CMHC verifying the provision of core services.

If the RO or CMS-contracted personnel plans to perform a site visit of an existing, enrolled CMHC, the intermediary shall furnish any and all background information requested by the RO. All inquiries and correspondence relating to the site visit shall be directed to the RO.

Prior to making a recommendation for approval or denial, the intermediary shall ensure that the provider has submitted a completed and signed CMHC attestation statement. If the CMHC does not submit one, the intermediary shall recommend denial. (The attestation requirement also applies to new owners in a CHOW.) The CMHC attestation statement typically serves as the provider agreement.

If the intermediary issues a recommendation for approval, it shall send a copy of the Form CMS-855A to the State agency (or, for intermediaries in RO 9, the intermediary's RO) with its recommendation. The intermediary shall also contact the appropriate RO to initiate a site visit of the CMHC applicant; a copy of the request should be sent to the State agency.

C. Practice Locations/Alternative Sites

A CMHC must list in Section 4 of its Form CMS-855A all alternative sites where core services are provided (i.e., proposed alternative sites for initial applicants and actual alternative sites for those CMHCs already participating in Medicare). The RO will decide whether the site in question: (1) can be part of the CMHC's enrollment (i.e., a practice location), or (2) should be enrolled as a separate CMHC with a separate provider agreement. The practice location could be out-of-state if the RO determines that the location services the same "defined geographic area" as the main location. In all cases, the RO has the final call in determining whether a particular practice location qualifies as an alternative site or whether a separate enrollment, provider agreement, etc., is required.

Contractors may refer to Pub. 100-07, SOM, chapter 2, section 2252, for additional information on CMHC alternative sites. Particular attention should be paid to the following provisions in section 2252I, regarding alternative sites:

- If a CMHC operates a CMS-approved alternative site, the site is not required to provide all of the core services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC.

- RO approvals of such alternative sites should be very limited, as CMHCs must serve a distinct and definable community and also because CMS has not limited

the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities.

- The RO will inform the CMHC if it determines that the proposed alternative site must be separately approved because it is not a part of the community where the CMHC is located.

D. Additional CMHC Information

For more information on CMHCs, refer to the following:

- Section 1861(ff) of the Social Security Act;
- 42 CFR Parts 410.2, 410.43, and 410.110; and
- Pub. 100-07, chapter 2, sections 2250 – 2252P (State Operations Manual).

15.4.1.2 - Comprehensive Outpatient Rehabilitation Facilities (CORFs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. Specific examples of such services include:

- Physician services (*)
- Physical therapy (*)
- Occupational therapy
- Respiratory therapy
- Speech pathology
- Social work or psychological services (*)
- Prosthetic/orthotic devices
- Lab services (must meet 42 CFR Part 493 requirements)

* Services that the CORF must provide

In addition:

- If the RO determines that sufficient functional and operational independence exists, a CORF may be able to share space with another Medicare provider. However, the CORF may not operate in the same space at the same time with another Medicare provider. (See Pub. 100-07, State Operations Manual, chapter 2, sections 2364 – 2364C for more information.)

- Like most certified providers, CORFs must be surveyed by the State agency and must sign a provider agreement.

- On occasion, an outpatient physical therapy/speech language pathology (OPT/SLP) location might convert to a CORF; of course, it must be surveyed to ensure the CORF conditions of participation are met prior to receiving a Medicare provider number.

B. CORF Enrollment

Notwithstanding the "single fixed location" language cited in subsection A above, there may be isolated cases where the RO permits a CORF to have an offsite location. This typically arises if the CORF wants to provide physical therapy (PT), occupational therapy (OT), or speech language pathology (SLP) services away from the primary location. (This is permitted under 42 CFR §485.58(e)(2)). The offsite location would not necessarily be separately surveyed, but would be listed as a practice location on the CORF's Form CMS-855A.

For more information on CORFs, refer to:

- Section 1861(cc) of the Social Security Act;
- 42 CFR Part 485, Subpart B;
- Pub. 100-07, chapter 2, sections 2360 – 2366 (State Operations Manual);
- Pub. 100-07, chapter 3, section 3224 (State Operations Manual);
- Pub. 100-07, Appendix K (State Operations Manual); and
- Pub. 100-02, chapter 12 (Benefit Policy Manual).

15.4.1.3 - End-Stage Renal Disease Facilities (ESRDs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Types of ESRDs

The ESRD facilities are entities that perform renal services for patients with irreversible and permanent kidney failure. There are several types of ESRD facilities:

- Renal Transplantation Center (RTC) – An RTC is a hospital unit approved to furnish – directly - transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. An RTC must be a member of the Organ Procurement and Transplantation Network (OPTN).

- Renal Dialysis Center (RDC) – An RDC is a hospital unit approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement and outpatient dialysis). Also:

- The RDC need not furnish transplantation services;

- An RTC can also be an RDC;

- The RDC must be hospital-owned and operated, and the hospital must be enrolled in Medicare.

A separate, independent dialysis unit located in a Medicare-approved hospital cannot be approved as an RTC or RDC. (See 100-07, SOM, chapter 2, section 2280.1.)

- Renal Dialysis Facility (RDF) – This is a unit (but not necessarily a hospital unit) approved to furnish dialysis services directly to ESRD patients. A hospital (whether enrolled or not) can be an RDF if it is an outpatient provider of dialysis services that will not be furnishing inpatient dialysis services.

- A hospital-based RDF "satellite" is one that is hospital-owned and administered but is not located on the hospital's premises. A hospital can have multiple satellites.

- Self-Dialysis Unit (SDU) – An SDU is a unit of an approved RTC, RDC or RDF and that provides self-dialysis services.

- Special Purpose Renal Dialysis Facility (SPRDF) – SPRDFs are entities that perform ESRD services on a short-term basis in special situations for patients who cannot otherwise receive treatment in the geographical area. SPRDFs can be approved to serve vacation areas and in emergency situations. (See Pub. 100-07, chapter 2, section 2280D for more information on SPRDFs.) Like RTCs, RDCs, RDFs, and SDUs, SPRDFs must submit a Form CMS-855A to the fiscal intermediary.

B. ESRD Survey and Certification

The standard CMS survey and certification form used for ESRDs is the Form CMS-3427. Part I of this form must be completed, as must the Form CMS-855A, when the ESRD is initially enrolling, changing or adding a location, or undergoing a CHOW. Part I must also be completed for: (1) a change in service and (2) an expansion or addition of ESRD stations. However, the Form CMS-855A need not be furnished in these two latter instances (e.g., an ESRD station does not qualify as a practice location on the Form CMS-855A), though the RO may issue a tie-in notice to the intermediary as notification of the change. Also, because the "End-Stage Renal Disease Facility" category on the Form CMS-855A encompasses all five ESRD categories, it is not necessary for the facility to submit a Form CMS-855A if it is changing from one ESRD type to another, though it must complete the Form CMS-3427. (See Pub. 100-07, SOM, chapter 2, sections 2274 – 2276 and 2278 – 227, for more information on the Form CMS-3427 requirement.)

If the RO approves the station/service change or addition, it may send a tie-in notice to the intermediary updating the number of stations or types of services.

C. Miscellaneous ESRD Policies

- The ESRD Network is a group of organizations under contract with CMS that serve as liaisons between the agency and ESRD providers. (There are currently 18 Network organizations.) The organizations oversee the care ESRD patients receive, collect data, and furnish technical assistance to ESRD providers and patients.

- The provider-based rules for ESRD facilities are contained in 42 CFR §413.174 and are slightly different than those listed in the main provider-based regulation (42 CFR §413.65). (§413.174 uses the term "hospital-based" as opposed to "provider-based.")

- As ESRD facilities are technically "suppliers," they sign a supplier agreement rather than a provider agreement. Even if the ESRD facility is a hospital unit, it signs an agreement that is separate and distinct from the hospital's agreement.

D. ESRD Enrollment

Each type of ESRD must enroll as an ESRD facility via the Form CMS-855A. Since the Form CMS-855A does not distinguish between the different types of ESRDs, the following general principles apply:

- If an enrolled RTC also wants to become an RDC, the provider must submit a new, complete Form CMS-855A for the RDC. For enrollment purposes, the RTC and the RDC will be treated as two separate ESRD facilities.

- If an enrolled ESRD wants to change to another type of ESRD, the provider need not submit a Form CMS-855A change of information (assuming that this is the only change to the provider's enrollment data).

- ESRD facilities can have multiple practice locations – if the RO approves it - though this typically only occurs with RDFs.

E. Additional Information on ESRD Facilities

For further data on ESRD facilities, refer to:

- Section §1881 of the Social Security Act;
- 42 CFR Part 405, Subpart U;

- Pub. 100-07, chapter 2, section 2270 – 2287B (State Operations Manual);

- Pub. 100-02, chapter 11 (Benefit Policy Manual); and

- Pub. 100-04, chapter 8 (Claims Processing Manual).

15.4.1.4 - Federally Qualified Health Centers (FQHCs)
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The FQHCs furnish services such as those performed by physicians, nurse practitioners, physician assistants, clinical psychologists, and clinical social workers. This includes certain preventive services like prenatal services, immunizations, blood pressure checks, hearing screenings and cholesterol screenings. (See Pub. 100-02, Medicare Benefit Policy Manual, chapter 13). Even though their services are billed to fiscal intermediaries, they are considered Part B certified suppliers.

The FQHCs are not required to obtain a State survey; there is little State agency involvement with FQHCs. As such, the intermediary will make its recommendation for approval or denial and forward it directly the RO. The RO will then make the final decision as to whether the supplier qualifies as a FQHC. Generally, in order to so qualify the facility must be receiving, or be eligible to receive, certain types of Federal grants (sometimes referred to as "grant status"), or must be an outpatient facility operated by an Indian tribal organization. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS) may assist the RO in determining whether a particular supplier meets FQHC standards, since HRSA maintains a list of suppliers that met certain grant requirements. (See Pub. 100-07, SOM, chapter 2, sections 2825-2826D for more information.)

A few other notes about FQHCs:

- As stated above, there is no State agency involvement with FQHCs. However, FQHCs still must meet all applicable State and local requirements and submit all applicable licenses. Typically, HRSA will verify such State/local compliance by asking the FQHC to attest that it meets all State/local laws.

- The FQHCs can be based in a rural or urban area.

- To qualify as an FQHC, the facility must, among other things, either: (1) furnish services to a medically underserved population or (2) be located in a medically underserved area.

- The effective date for an FQHC's Medicare participation is the date the RO signs the FQHC agreement after determining that all Medicare requirements, including enrollment requirements, are met. However, if the application is complete and all requirements have been met when the RO reviews the application, the RO will use the date on the intermediary's recommendation letter as the effective date. (See Pub. 100-07, chapter 2, section 2826H).

- The FQHC must submit a signed and dated attestation statement (Exhibit 177). This attestation serves as the Medicare FQHC benefit (or provider/supplier) agreement. (See Pub. 100-07, chapter 2, section 2826B.) The FQHC must also submit, as

indicated above, a HRSA "Notice of Grant Award" or Look-Alike Status. A completed FQHC crucial data extract sheet (Exhibit 178), however, is no longer required.

- The FQHC's cannot have multiple sites or practice locations. Each location must be separately enrolled and will receive its own OSCAR number.

For additional general information on FQHCs, refer to:

- Section 1861(aa)(3-4) of the Social Security Act;
- 42 CFR Part 491;
- Pub. 100-07, chapter 2, sections 2825 – 2826H (State Operations Manual);
- Pub. 100-04, chapter 9 (Claims Processing Manual); and
- Pub. 100-02, chapter 13 (Benefit Policy Manual)

For information on the appropriate contractor jurisdictions for incoming FQHC enrollment applications, see;

- Pub. 100-04, chapter 1, section 20;
- Pub. 100-04, chapter 9, section 10.3;
- CMS Change Request 6207.

15.4.1.5 – Histocompatibility Laboratories

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A histocompatibility laboratory does "matching" tests in preparation for procedures such as kidney transplants, bone marrow transplants, and blood platelet transfusions. It is the only type of laboratory that must enroll with the fiscal intermediary. Each histocompatibility lab must meet all applicable requirements in 42 CFR Part 493 (see 42 CFR §493.1278 in particular) and undergo a State survey.

For information on the appropriate contractor jurisdiction for incoming histocompatibility lab applications, please see Pub. 100-04, CPM, chapter 1, section 20.

15.4.1.6 - Reserved

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.1.7 - Hospices

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Hospices are not precluded from having multiple practice locations if permitted by the RO. If the RO disapproves the additional practice location, the location must seek Medicare approval as a separate hospice with its own Form CMS-855A enrollment, provider agreement and provider number. (See Pub. 100-07, SOM, chapter 2, section 2081, for the policies regarding multiple hospice locations.)

For more information on hospices, refer to:

- Sections 1861(u) and 1861(dd) of the Social Security Act;
- 42 CFR Part 418;
- Pub. 100-07, chapter 2, sections 2080 – 2087 (State Operations Manual);
- Pub. 100-04, chapter 11 (Claims Processing Manual); and
- Pub. 100-02, chapter 9 (Benefit Policy Manual)

15.4.1.8 - Hospitals and Hospital Units

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

- **Swing-Bed Designation** - A "swing-bed" hospital is one that is approved by CMS to furnish post-hospital SNF services. That is, hospital (or critical access hospital (CAH)) patients' beds can "swing" from furnishing hospital services to providing SNF care without the patient necessarily being moved to another part of the building. It receives a separate survey and certification from that of the hospital; thus, if swing-bed designation is terminated, the hospital still maintains its certification. In addition, the hospital is given an additional OSCAR number to bill for swing-bed services. (The third digit of the number will be the letter U, W, Y or Z.)

As stated in 42 CFR §482.66, in order to obtain swing-bed status the hospital – among other things – must: (1) have a Medicare provider agreement, (2) be located in a rural area, and (3) have fewer than 100 non-newborn or intensive care beds. Swing-bed hospitals, therefore, are generally small hospitals in rural areas where there may not be enough skilled nursing facilities; the hospital can thus be used to furnish SNF services.

A separate provider agreement and enrollment for the swing-bed unit is not required. (The hospital's provider agreement incorporates the swing-bed services.) The hospital can add the swing-bed unit as a practice location to its Form CMS-855A.

Additional data on "swing-bed" units can be found in Pub. 100-07, SOM, chapter 7, sections 2036 – 2040.

- **Psychiatric and Rehabilitation Units** – Though these units receive a State survey, a separate provider agreement and enrollment is not required. (The hospital's

provider agreement incorporates these units.) The hospital can add the unit as a practice location to the Form CMS-855A.

- **Multi-Campus Hospitals** - A multi-campus hospital (MCH) is one with two or more hospital campuses operating under one OSCAR number; the MCH would report its various units/campuses as practice locations on the Form CMS-855A. A hospital that has its own main campus but also occupies space in another hospital has a "satellite facility" in that other hospital. For additional information on multi-campus hospitals, see Pub. 100-07, chapter 2, section 2024.

15.4.1.9 - Indian Health Services (IHS) Facilities

(Rev. 358, Issued: 10-28-10, Effective: 11-29-10, Implementation: 11-29-10)

A. General Background Information

For purposes of provider enrollment only, there are several types of IHS facilities: (1) those that are wholly owned and operated by the IHS, (2) facilities owned by the IHS but tribally operated, and (3) facilities totally owned and operated by a tribe, though under the general IHS umbrella. When an IHS facility wishes to enroll with the fiscal intermediary, it may either check: (a) "Indian Health Services Facility", or (b) the specific provider type it is. For instance, if an IHS hospital is involved, the provider may check "Indian Health Services Facility" or "Hospital" on the application - or perhaps both. Even if it only checked "Hospital," the LBN or DBA Name will typically contain some type of reference to Indian Health Services; as such, the intermediary will know it is dealing with an IHS facility.

The overwhelming majority of IHS facilities on the Part A side are either hospitals, SNFs, CAHs, or ESRD facilities. The contractor processes IHS applications in the same manner (and via the same procedures) as it would with a hospital, SNF, etc. (This also applies to procedures for PECOS entry.)

As for CCN numbers, the IHS facility uses the same series that its concomitant provider type does. In other words, an IHS hospital uses the same CCN series as "regular" hospitals; an IHS CAH utilizes the same series as regular CAHs; and so forth.

For additional general information on IHS facilities, see Pub. 100-04, chapter 19. For information regarding the appropriate contractor jurisdiction for incoming Part A IHS facility applications, see Pub. 100-04, chapter 1, section 20.

B. IHS Enrollment

Effective September 1, 2010, IHS facilities and tribal providers seeking to initially enroll in the Medicare Program or submit a change of information may utilize Internet-based PECOS or use the paper form CMS-855 enrollment application.

If IHS facilities or tribal providers choose to use Internet-based PECOS, they will be responsible for mailing to TrailBlazer Health Enterprises, LLC. (TrailBlazer), the designated Medicare contractor, the following:

- A cover letter to indicate they are seeking to enroll as an IHS facility or tribal provider or updating their current enrollment information;
- The Internet-based PECOS certification statement; and
- Any other applicable supporting documentation.

If the IHS facility or tribal provider sends this information to a Medicare contractor other than Trailblazer, that contractor shall forward the information directly to Trailblazers at one of the following addresses:

Part A Provider Enrollment
TrailBlazer Health Enterprises, LLC
Provider Enrollment
P.O. Box 650458
Dallas, TX 75265-0458

Part B Provider Enrollment
TrailBlazer Health Enterprises, LLC
Provider Enrollment
P.O. Box 650544
Dallas, TX 75265-0544

Upon receipt of the cover letter, the PECOS certification statement and supporting documentation, TrailBlazer, within 10 calendar days, shall request the PECOS development team transfer the Internet-based PECOS enrollment application from the designated State carrier or A/B MAC to Trailblazers, via Share Point. Trailblazer shall also notify the carrier or A/B MAC involved of their request so that no further action on the Web-generated logging and tracking (l&t) record is taken.

This interim process shall remain in effect until PECOS system changes are implemented to route all electronic enrollment applications received by IHS facilities and tribal providers directly to Trailblazers.

15.4.1.10 - Organ Procurement Organizations (OPOs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

An OPO is an organization that performs or coordinates the procurement, preservation, and transport of organs, and maintains a system for locating prospective recipients for available organs. There are two general steps involved in becoming a Medicare OPO – certification and designation.

Certification means that CMS has determined that an OPO meets the requirements for

certification at 42 CFR §486.303. It does not mean, however, that the OPO can begin billing for services. First, CMS must assign (or "designate") a geographic service area to the OPO. (The provider must also complete the Form CMS-576, Request for OPO Designation.) In practical terms, "designation" means that CMS has approved the OPO for coverage of services to transplant centers and that the OPO can begin submitting claims to Medicare.

There can be only one designated OPO per geographic service area. When an OPO is de-certified and its service area is opened for competition, the applicable CMS RO publishes a notice in local newspapers. CMS then selects an OPO to take over the service area, using the process at 42 CFR §486.316. As stated above, the OPO that CMS selects must first have been certified by CMS and the OPO must also meet the qualifications for designation at 42 CFR §486.304. The OPO must sign a provider agreement (Form CMS-576A) and participate in the Organ Procurement and Transplantation Network (OPTN). (See Pub. 100-07, chapter 2, sections 2810 and 2811.) Note that OPOs do not receive a State survey.
For more information on OPOs, refer to:

- Section 1138 of the Social Security Act;
- 42 CFR §486.301 - §486.348; and
- Pub. 100-07, chapter 2, sections 2810 – 2819 (State Operations Manual).

For guidance on the appropriate contractor jurisdiction for incoming OPO applications, please see Pub. 100-04, CPM, chapter 1, section 20. Note that a hospital-based OPO must enroll separately, be separately certified, and sign its own provider agreement. However, the hospital's Medicare contractor will service the OPO and the OPO will not receive its own CCN number.

15.4.1.11 - Outpatient Physical Therapy and Speech Language Pathology (OPT/SLP)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

There are three types of certified providers of OPT/SLP services:

- **Rehabilitation Agencies** – These facilities furnish services in a team environment and in accordance with a "multidisciplinary" program to assist handicapped and disabled individuals. They provide not only OPT or SLP services, but social or vocational adjustment services as well. (See Pub. 100-07, SOM, chapter 2, section 2292A.) The overwhelming majority of Part A OPT/SLP providers are rehabilitation agencies.

- **Clinics** – A clinic is created primarily for the provision of outpatient physician services. The entity's services must be furnished by a group of at least three physicians practicing medicine together, and at least one physician must be present in the clinic at all times to perform medical services.

- **Public Health Agency** – This is an agency created by a State or local government. Its primary purpose is to furnish environmental health services, preventive medical services and, in some instances, therapeutic services, as a means of sustaining the health of the general population.

Note further that:

- If an OPT/SLP provider elects to convert to a CORF, it must meet the CORF conditions of coverage and participation. A new Form CMS-855A enrollment application, State survey, and RO approval are also required.

- Only those clinics, as listed above, that provide OPT/SLP services have provider agreements under 42 CFR §489.2. Part B physician groups – the supplier type that most people normally associate with the term "clinics" – do not have provider or supplier agreements.

- Occupational therapy cannot be substituted for the physical therapy requirement. It may, however, be provided in addition to physical therapy or speech language pathology services. (See Pub. 100-07, SOM, chapter 2, section 2292A.)

B. Extension Locations

As discussed in Pub. 100-07, SOM, chapter 2, section 2298A, an OPT/SLP provider can furnish services from locations other than its primary site. (The provider must designate one location as its primary location.) These sites are called extension locations, and may include freestanding offices, suites in an office or medical building, or even space in an existing Medicare provider, such as a SNF or hospital; however, the separate area of the host provider or facility must be set aside for the provision of OPT/SLP services during the hours of the OPT's operations. (The area/room/unit would be considered the extension location.)

An OPT/SLP may also provide therapy services in a patient's home or in a patient's room in a SNF. Because they are not considered extension locations, neither the home nor a patient's room need be listed as a practice location on the provider's Form CMS-855A. (See Pub. 100-07, SOM, chapter 2, section 2298B.)

For an OPT/SLP provider to establish an extension location in an adjoining State, the two States involved must have a signed reciprocal agreement with each other allowing approval of the extension location. An extension location situated in a different State will bill under the primary site's provider number. (See Pub. 100-07, SOM, chapter 2, section 2302.)

C. Additional OPT/OSP Information

For more information on OPT/SLP providers refer to:

- Section 1861(p) of the Social Security Act;
- 42 CFR Part 485, subpart H;
- Pub. 100-07, chapter 2, sections 2290 – 2306 (State Operations Manual); and
- Pub. 100-07, Appendix E (State Operations Manual).

15.4.1.12 - Religious Non-Medical Health Care Institutions (RNCHIs)
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

RNHCIs furnish only nonmedical nursing services and items to people who choose to rely solely on obtaining a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious views. Such nonmedical services are performed by nonmedical nursing personnel and include activities like assistance in moving, comfort and support measures, and general assistance in performing day-to-day activities. (Of course, the nonmedical nursing personnel must be experienced in caring for the physical needs of nonmedical patients.) RNHCIs do not perform any medical screenings, examinations, diagnoses, or treatments, including the administration of drugs. It should also be noted that each beneficiary who wishes to receive services in an RNHCI must make a valid and formal written statement (or "election") to do so. (The specific election requirements are discussed in 42 CFR §403.724 and Pub. 100-07, SOM, chapter 2, section 2054.1B.)

The Boston RO, has primary responsibility over the approval and certification of RNHCIs. RNHCIs are not certified by the State, but must meet all of the conditions of coverage outlined in 42 CFR §403.720, as well as all conditions of participation outlined in 42 CFR §403.730 through 746. For purposes of provider enrollment, the two most important conditions are:

- The provider must not be owned by, under common ownership with, or have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services. (Permissible affiliations are described in 42 CFR §403.738(c)); and
- The provider must be a non-profit organization per subsection (c)(3) of § 501 of the Internal Revenue Code of 1986, and exempt from taxes under subsection 501(a).

To this end, the contractor shall closely examine Sections 5 and 6 of the CMS-855A, as

well as verify the provider's non-profit status, to ensure that the two aforementioned requirements are met.

For more information on RNCHIs, refer to:

- Section 1861(ss)(1) of the Social Security Act;
- 42 CFR Part 403, subpart G;
- Pub. 100-07, SOM, chapter 2, sections 2054, 2054.1, 20541A and 2054.1 (State Operations Manual);
- Pub. 100-04, chapter 3, sections 170 - 180 (Claims Processing Manual); and
- Pub. 100-02, chapter 1, sections 130 – 130.4.2 (Benefit Policy Manual).

For guidance on the appropriate contractor jurisdiction for incoming RNCHI applications, please see Pub. 100-04, chapter 1, section 20.

15.4.1.13 - Rural Health Clinics (RHCs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

Rural health clinics (RHCs):

- Are considered to be Part B certified suppliers, even though they enroll with and bill fiscal intermediaries.
- Must be primarily engaged in furnishing outpatient services. However, the services can in certain instances be performed in locations outside of the four walls of the clinic. (See Pub. 100-02, chapter 13 for more information.)

There are certain services performed by RHCs that do not actually qualify as RHC services. As such, they must be billed to the carrier – meaning that the clinic must enroll with the carrier as a "Multi-Specialty Clinic." It is not uncommon to see RHCs enrolled with both the intermediary (to get paid for RHC services) and the carrier (to get paid for non-RHC services).

- Sign a supplier agreement with CMS (akin to those signed by certified providers). Specifically, RHCs sign the Health Insurance Benefit Agreement (Form CMS-1561A).
- Can be either mobile in nature or fixed/permanent locations.

Note that a facility cannot be simultaneously enrolled as an FQHC and an RHC. Though there are similarities between these two provider types, there are key

differences:

- Unlike FQHCs, which can service rural or urban regions, an RHC may only service an area that: (1) is rural, and (2) contains a shortage of health services or qualified medical personnel, otherwise known as a "shortage area." (See Pub. 100-02, chapter 13, section 10, which states that RHCs are clinics located in areas that are designated both by the Bureau of the Census as rural and by the Secretary of DHHS or the State as medically underserved.)

- FQHCs furnish preventive services while RHCs do not.

- RHCs are surveyed by the State; FQHCs are not.

B. Additional RHC Information

For more information on RHCs, refer to:

- Section 1861(aa)(1-2) of the Social Security Act;

- 42 CFR Part 491, subpart A;

- Pub. 100-07, chapter 2, sections 2240 – 2249 (State Operations Manual);

- Pub. 100-04, chapter 9 (Claims Processing Manual); and

- Pub. 100-02, chapter 13 (Benefit Policy Manual).

For guidance on the appropriate contractor jurisdictions for incoming RHC applications, please see:

- Pub. 100-04, chapter 1, section 20;

- Pub. 100-04, chapter 9, section 10.3;

- CMS Change Request 6207.

15.4.1.14 - Skilled Nursing Facilities (SNFs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

As stated in Pub. 100-07, chapter 7, section 7004B, a SNF is an entity that:

- Is primarily engaged in providing to residents skilled nursing care and related services for residents who require medical or nursing care; or

- Is primarily engaged in providing to residents skilled rehabilitation services for the rehabilitation of injured, disabled, or sick persons and is not primarily for the care and treatment of mental diseases;

- Has in effect a transfer agreement (meeting the requirements of §1861(1) of the Social Security Act with one or more hospitals having agreements in effect under §1866 of the Social Security Act); and

- Meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of §1819 of the Social Security Act.

A SNF may provide Part B outpatient physical therapy, speech therapy, or occupational therapy services either directly or under arrangement. (See Pub. 100-07, chapter 7, section 7010.)

As stated above, a SNF must have a "transfer agreement" with a Medicare-enrolled hospital. The agreement must provide for the transfer of patients between the hospital and the SNF, as well as the interchange of patient information. This requirement is needed since patients that are discharged from hospitals may then go to a SNF for follow-up or additional nursing care. The transfer agreement need not be submitted with the SNF's Form CMS-855A enrollment application; the State and/or RO will verify that the agreement exists.

Like other certified providers, SNFs receive a State survey and sign a provider agreement. Note that it is extremely rare for a SNF to have multiple practice locations; in any event, the RO will make the final decision as to whether the site can be treated as a practice location or must enroll as a separate SNF.

B. SNF Distinct Parts

A SNF can be a separate institution or a "distinct part" of an institution. The term "distinct part" means an area or portion of an institution (e.g., a hospital) that is certified to furnish SNF services. For instance, suppose Hospital X is located in a five-story building. The fifth floor is reserved for SNF services. For enrollment and certification purposes, and subject to RO approval, X could enroll as a hospital while the "5th floor" could enroll as a SNF. Of course, "distinct part" is not just limited to physical considerations. The distinct part must be fiscally separate from the other institution with respect to cost reporting. The hospital and the SNF distinct part will each receive a separate provider number, and separate Forms CMS-1539 will be prepared. Also:

- A hospital is permitted to have only one SNF distinct part.

- The hospital will typically submit to the State a diagram/floor plan outlining the distinct part's area.

- "Distinct part" designation is not the same thing as being "provider-based." (A provider-based SNF, like a distinct part SNF, receives an OSCAR number separate from that of the hospital.)

A SNF distinct part unit must enroll separately (it cannot be listed as a practice location on the hospital's Form CMS-855A), be separately surveyed and sign a separate provider agreement. (Note how this is different from "swing-bed" units, which do not enroll separately and do not sign separate provider agreements.) (See Pub. 100-07, chapter 2, section 2762B, subsection 4, for more information on SNF distinct parts.)

C. Additional Information

For more information on SNFs, refer to:

- Section 1819(a) of the Social Security Act;
- 42 CFR Part 488, subpart E;
- Pub. 100-07, chapter 7 (State Operations Manual);
- Pub. 100-02, chapter 8 (Benefit Policy Manual); and
- Pub. 100-04, chapter 6 (Part A) and chapter 7 (Part B) (Claims Processing Manual).

15.4.2 – Carrier-Enrolled Organizational Suppliers
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.2.1 - Ambulatory Surgical Centers (ASCs)
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

An ASC is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. The ASC signs a supplier agreement (Form CMS-370) with CMS and enrolls with the carrier; the supplier agreement is very similar to provider agreements signed by Part A providers. Note that ASCs can be fixed locations or mobile in nature.

Under 42 CFR §416.26(a), CMS may deem an ASC to be in compliance with the ASC conditions of coverage if the ASC:

- Is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;

- In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and

- The ASC authorizes the release to CMS, of the findings of the accreditation survey.

- Unless CMS deems the ASC to be in compliance with the ASC conditions of coverage, a State survey will be performed.

B. ASCs and Hospitals

There are three main enrollment situations involving ASCs and hospitals:

1. The ASC is operated by a hospital – If the ASC is operated by a hospital, the ASC enrolls, participates and is paid only as an ASC. In other words, it still must independently enroll with the carrier and cannot be paid as a hospital outpatient department. The ASC agreement (Form CMS-370) will be made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC. Also, costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report. (See 42 CFR §416.30(f).)

2. Hospital outpatient department – If the ASC is treated as a hospital outpatient department, it will not independently enroll with the carrier as an ASC. It will simply be considered part of the hospital, and the services furnished therein will be billed to the fiscal intermediary. (See Pub. 100-04, chapter 14, section 10.1.)

3. The ASC is not hospital-operated (i.e., not a part of a provider of services or any other facility) – In this case, the ASC simply enrolls with the carrier normally.

In short, if an ASC is hospital-operated, it has the option of being covered under Medicare as an ASC, or of being treated as a hospital-affiliated outpatient surgery department. (See Pub. 100-02, chapter 15, section 260.1.) If a hospital-based facility decides not to become a certified ASC, it bills the fiscal intermediary via the Form CMS-1450.

C. Additional Information

For more information on ASCs, refer to:

- Section 5.6 of this manual;

- Section 1832(a)(2)(F) of the Social Security Act;

- 42 CFR Part 416;

- Pub. 100-07, chapter 2, section 2210 and Appendix L (State Operations Manual);

- Pub. 100-02, chapter 15, sections 260 – 260.5.3 (Benefit Policy Manual); and

- Pub. 100-04, chapter 14 (Claims Processing Manual).

- Also, see Pub. 100-07, chapter 2, section 2210, for information regarding the sharing of space between ASCs and other providers.

15.4.2.2 - CLIA Labs

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. General Background Information

Through the Clinical Laboratory Improvements Amendments (CLIA) program, CMS regulates all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of humans. CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate in order to operate. It is largely immaterial whether the entity itself is a lab (and does nothing but lab tests) or is a provider that performs many different types of services, of which lab testing is just a small part; laboratories are subject to CLIA- unless an exemption applies - regardless of the complexity or amount of testing that the laboratory will perform.

Under 42 CFR Part 493, all entities that perform laboratory testing must, among other things:

- Pay user fees as assessed by CMS to finance the administration of the CLIA program (the amount of the fee each lab pays depends largely on the type of certificate being requested and the complexity of the tests that will be performed);

- Undergo surveys to assess compliance with applicable CLIA requirements; and

- Apply for and obtain CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization.

Certain types of laboratories and laboratory tests are not subject to CLIA requirements. These include, but are not limited to:

- Entities (or components thereof) that perform testing strictly for forensic purposes;

- Research laboratories that test – but do not report - patient specific results (although they test human specimens) for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individuals;

- Laboratories licensed in a State whose laboratory licensure program is approved by CMS; and

- Facilities which serve only as collection stations.

(See Pub. 100-07, chapter 6, section 6002, for additional laboratories not subject to CLIA. Though these CLIA-exempt laboratories do not receive a CLIA certificate, they do receive a CLIA number for identification purposes.)

B. Form CMS-116 and CLIA Certificates

Prior to performing laboratory services - again, irrespective of whether it plans to enroll in Medicare - a laboratory must submit a Form CMS-116 to the local State Agency (which may also require the laboratory to complete State-specific forms). The Form CMS-116 requests information such as the:

- CLIA certificate being requested;

- Type of laboratory (e.g., hospital, physician office, ASC);

- Hours during which laboratory testing will take place;

- Sites where testing will occur; and

- Type of tests that will be performed.

After completing the Form CMS-116, the lab must be inspected (unless the lab meets the requirements for a Certificate of Waiver). The survey will typically be performed by CMS, with two key exceptions:

- If the lab is located in a CLIA-exempt State – meaning that the State's standards for labs meet or exceed CLIA standards – the State itself will conduct the inspection. (Not surprisingly, these labs are known as "CLIA-exempt labs." While they are not required to obtain a CLIA certificate, they still receive a CLIA number for payment purposes.)

- If the lab seeks accreditation (in lieu of a CMS survey) by a CMS-approved accrediting body, that body will conduct the survey.

State agencies are responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. The SA recommends to the RO whether to certify the laboratory.

There are several types of CLIA certificates, including:

- Certificate of Waiver (COW) – There are certain laboratory tests that are "waived," meaning that the laboratory is not subject to routine CLIA inspections. In general, waived tests have been determined by Centers for Disease Control (CDC) and/or Food and Drug Administration (FDA) to be so simple that there is minimal risk of error. If a COW is issued, the laboratory can only perform waived tests, must still register with CLIA, and pay all necessary fees; CLIA laboratories are not CLIA-exempt.

- Certificate of Accreditation – Issued when a lab meets the standards of a CMS-approved accreditation organization and this is verified by the latter. The laboratory will identify on the Form CMS-116 the organization from which it has received accreditation.

- Certificate for Provider-Performed Microscopy (PPM) Procedures - Issued if the laboratory indicates that a physician or practitioner performs only the microscopy tests listed at 42 CFR 493.19(c), or performs only the listed microscopy tests in any combination with waived tests.

- Certificate of Compliance – Issued when it is determined through a survey to be in compliance with applicable requirements for laboratories performing tests of moderate and/or high complexity.

If the laboratory is applying for a Certificate of Compliance or Certificate of Accreditation, it will initially pay for and receive a Registration Certificate.

The State agency is responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. It will send to the RO its recommendation as to whether the laboratory should be certified.

C. CLIA Enrollment

Note the following on CLIA Medicare enrollment:

- Prior to enrolling the laboratory, the contractor shall require a Certificate of Waiver, Compliance, Accreditation, PPM Procedures, or Registration.

- Each practice location at which laboratory tests are performed must submit to the contractor a separate CLIA certificate for that location. The only exceptions to this rule are:

    - Laboratories within a hospital that are located at contiguous buildings, on the same campus, and under common direction;

- Non-profit or governmental laboratories that engage in limited public health testing;
- Laboratories that are not at a fixed location (i.e., are mobile)

(See Pub. 100-07, chapter 6, sections 6008, 6026 and 6034 – 6036A for more information.)

- The laboratory must submit to the contractor a separate certificate for each State in which testing is performed.

- If a lab is under the same ownership and at the same location as the "main provider," it generally does not need to enroll separately. The enrolling provider will just furnish its CLIA number in the practice location section. Conversely, if a lab is an "independent CLIA lab," it must enroll separately.

- A separate enrollment record need not be created for each CLIA number. For instance, suppose a physician is enrolling in Medicare and has a CLIA number. The carrier need only create a single enrollment record that will encompass the Medicare number and the CLIA number.

- The CLIA number is a 10-digit number, and the CLIA data system is a subset of the OSCAR system.

D. Additional Information

For additional data on CLIA laboratories, refer to:

- 42 CFR Part 493;
- Publication 100-07, chapter 6 (State Operations Manual);
- Publication 100-04, chapter 16 (Claims Processing Manual); and
- Form CMS-116 (CLIA Application for Certification).

15.4.2.3 - Mammography Screening Centers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in 42 CFR §410.34(a)(2), a screening mammography is a radiological procedure "furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure." All mammography centers must apply for and receive certification from the Food and Drug Administration (FDA), which is responsible for collecting certificate fees and surveying mammography facilities (screening and diagnostic). The FDA provides CMS with a listing of all providers that have been issued certificates to perform mammography services and CMS notifies contractors

accordingly.

Prior to enrollment, the contractor shall require the center to submit a copy of its FDA certificate. Note that per 42 CFR §410.34 (a)(7)(i), the contractor may accept a "provisional" certificate.

For more information on mammography screening centers, refer to:

- §1834(c) of the Social Security Act
- 21 CFR Part 900
- 42 CFR §410.34
- Pub. 100-04, chapter 18, sections 20 through 20.8 (Claims Processing Manual)
- Pub. 100-02, chapter 15, section 280.3 (Benefit Policy Manual)

15.4.2.4 - Pharmacies

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Pharmacies typically enroll with the NSC. However, there are certain covered drugs that are billed through the physician fee schedule and not the DMEPOS schedule. Such drugs must be billed to the carrier and, therefore, any pharmacy furnishing them must enroll with the carrier via a CMS-855B.

See Pub. 100-04, chapter 17 and Pub. 100-02, chapter 15, sections 50 through 50.6, for more information on the billing procedures for drugs.

15.4.2.5 - Portable X-Ray Suppliers (PXRSs)

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

A. General Background Information

A portable x-ray supplier (PXRS) moves its x-ray equipment from place to place, performing x-ray services at various locations. To qualify as a PXRS, an entity must meet the conditions for coverage discussed in 42 CFR §486.100-110. These include, but are not limited to:

- Possess a State license or registration to perform the services (assuming the State licenses/registers PXRSs) (42 CFR §486.100(a));
- All personnel operating the equipment are licensed/registered in accordance with State and local laws (and meet certain other training requirements) (42 CFR §486.100(b));

- All PXRS equipment is licensed/registered in accordance with State and local laws (42 CFR §486.100(c));

- All suppliers of PXRS agree to render such services in conformity with Federal, State and local laws relating to safety standards (42 CFR §486.100(d));

- The PXRS services are provided under the supervision of a qualified physician. (42 CFR §486.102(a)). Additionally, the supervising physician must either:

    - Own the equipment (which must be operated only by his/her employees); or

    - Certify on a yearly basis that he/she periodically checks the procedural manuals and observes the operators' performance, and that the equipment and personnel meet all Federal, State, and local requirements

- The PXRS are provided under the supervision of a licensed doctor of medicine or osteopathy who is qualified in advanced training and experience in the use of x-rays for diagnostic purpose (42 CFR §486.102(b));

- The PXRS has an orientation program for its personnel (42 CFR §486.104(b));

- All equipment is inspected at least every 2 years. (42 CFR §486.110).

A PXRS can be simultaneously enrolled as a mobile IDTF, though they cannot bill for the same service. Note that PXRSs require a State survey, while mobile IDTFs do not (although IDTFs do require a site visit); moreover, PXRSs can bill for transportation and set-up, while mobile IDTFs cannot.

PXRSs do not have a supplier agreement.

B. Enrollment of PXRS

In order to enroll as a PXRS, a supplier must complete a Form CMS-855B, undergo a State survey, and secure RO approval. One of the most important parts of any PXRS's enrollment application is Section 4. Here, the PXRS must furnish, among other things, the following information:

- Whether it furnishes services from a "mobile facility" or "portable unit." The former term typically describes a vehicle that travels from place to place to perform services <u>inside</u> the vehicle. Examples of such vehicles include mobile homes or trailers. A "portable unit" exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment on a portable unit is separate from and unattached to the vehicle.

- A PXRS can be either a mobile facility or portable unit, although it usually is the latter. A mobile IDTF, on the other hand, while it too can be either, is typically a mobile facility.

- Its base of operations. This is where personnel are dispatched from and where equipment is stored. It may or may not be the same address as the practice location(s).

- All geographic locations at which services will be rendered.

- Vehicle information IF the services will be performed inside or from the vehicle. Copies of all licenses and registrations must be submitted as well.

As stated in Pub. 100-07, chapter 2, section 2422, the "residence used as the patient's home" can include a SNF or hospital that does not provide x-ray services for its patients and arranges for these services through a PXRS, such as a mobile unit. However, the mobile unit can neither be fixed at any one location nor permanently located in a SNF or a hospital.

C. Additional Information

For more information on PXRSs, refer to:

- Section 1861(s)(3) of the Social Security Act;

- 42 CFR Parts 486.100 – 486.110;

- Pub. 100-07, chapter 2, sections 2420 – 2424B (State Operations Manual);

- Pub. 100-02, chapter 15, sections 80.4 – 80.4.4 (Benefit Policy Manual); and

- Pub. 100-04, chapter 13, sections 90 – 90.5 (Claims Processing Manual).

15.4.2.6 - Radiation Therapy Centers
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42 CFR §410.35, Medicare Part B pays for x-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

For additional background on radiation therapy services, see:

- Section 1861(s)(4) of the Social Security Act;

- 42 CFR §410.35;

- Pub. 100-04, chapter 13; and

- Pub. 100-02, chapter 15, section 90.

15.4.2.7 - Suppliers of Ambulance Services
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per 42 CFR §410.40(d), Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated.

A. Types of Ambulance Services

There are several types of ambulance services covered by Medicare. They are defined in 42CFR §414.605 as follows:

1. **Advanced Life Support, level 1** (ALS1) - Transportation by ground ambulance vehicle, medically necessary supplies and services, and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

NOTE: Per 42CFR §414.605, ALS personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. The EMT-Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT-Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications.

2. **Advanced Life Support, level 2** (ALS2) - Either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the seven ALS procedures specified in 42CFR §414.605.

3. **Air Ambulance** (Fixed-Wing and Rotary-Wing) - Air ambulance is furnished when the patient's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, this type of transport may be necessary because: (1) the patient's condition requires rapid transport to a treatment facility and either greater distances or other obstacles (e.g., heavy traffic) preclude such rapid delivery to the nearest appropriate facility; or (2) the patient is inaccessible by ground or water vehicle.

4. **Basic Life Support** (BLS) - Transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT-

Basic).

5. **Paramedic ALS Intercept Services** (PI) - Per 42CFR §414.605, EMT-Paramedic services furnished by an entity that does not furnish the ground transport, provided that the services meet the requirements in 42CFR §410.40(c). PI typically involves an arrangement between a BLS ambulance supplier and an ALS ambulance supplier, whereby the latter provides the ALS services and the BLS supplier provides the transportation component. Per 42CFR §410.40(c), PI must meet the following requirements:

- Be furnished in an area that is designated as a rural area;

- Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

  - Are certified to furnish ambulance services as required under 42CFR §410.41.

  - Furnish services only at the BLS level.

  - Be prohibited by State law from billing for any service.

- Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

  - Is certified to furnish ALS services as required in 42CFR §410.41(b)(2).

- Bills of all the recipients who receive ALS intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

6. **Specialty Care Transport** (SCT) - Inter-facility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (e.g., nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.)

B. Ambulance Qualifications

1. Vehicle Design and Equipment

As specified in 42CFR §410.41(a), a vehicle used as an ambulance must meet the following requirements:

- Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

- Be equipped with emergency warning lights and sirens, as required by State or local laws.
- Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

- Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

2. Vehicle Personnel

Per 42CFR §410.41(b)(1)(i) & (ii), a BLS vehicle must be staffed by at least two people, one of whom must be: (1) certified as an emergency medical technician by the State or local authority where the services are furnished, and (2) legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

An ALS vehicle, in addition to meeting the BLS vehicle staff requirements described in 42CFR §410.41(b)(2), the previous paragraph, must also have one of the two staff members be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

C. Ambulance Claims Jurisdiction

Ambulance claims jurisdiction policies are specified in Pub. 100-04, chapter 1, section 10.1.5.3, and Pub. 100-04, chapter 15, section 20.1.2.

D. Completion of the CMS-855B

Pub. 100-02, chapter 10, section 10.1.3 states that, in determining whether the vehicles and personnel of the ambulance supplier meet all of the above requirements, the contractor may accept the supplier's statement (absent information to the contrary) that its vehicles and personnel meet all of the requirements. The contractor shall note that this provision in no ways obviates the need for the supplier to complete and submit to the contractor the CMS-855B enrollment form (including Attachment 1 thereto and all supporting documents), and does not excuse the contractor from having to verify the data on the CMS-855B enrollment form in accordance with the provisions of Pub. 100-08, chapter 10. In other words, the "statement" referred to in section 10.1.3, does not supplant or replace the CMS-855B provider enrollment process.

E. Miscellaneous Information

1. **Payment Amounts** - Per 42CFR §414.610(a), Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount.

2. **Non-Emergency Transport** - As stated in 42CFR §410.40(d), non-emergency transportation by ambulance is appropriate if either: (1) the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required.

3. **Point of Pick-Up** - The point of pick-up (POP), which is reported by the 5-digit ZIP Code, determines the basis of payment under the fee schedule. (See Pub. 100-04, chapter 15, section 20.1.5 for more information on the POP.)

4. **Destinations** - As discussed in 42CFR §410.40(e), Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

- From a hospital, CAH, or SNF to the beneficiary's home.

- From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

Per Pub. 100-02, chapter 10, section 10.3.8, ambulance service to a physician’s office is covered only if: (1) transport is en route to a Medicare-covered destination, as described in Pub. 100-02, chapter 10, section 10.3; and (2) during the transport, the ambulance stops at a physician's office because of the patient's dire need for professional attention, and immediately thereafter, the ambulance continues to the covered destination.

(See Pub. 100-02, chapter 10, section 10.3.2 for information on “institution-to-institution” ambulance services; as stated therein, there may be instances where the institution to which the patient is initially taken is found to have inadequate or unavailable facilities to provide the required care, and the patient is then transported to a second institution having appropriate facilities. Also see Pub. 100-02, chapter 10, section 10.4.4, for information on hospital-to-hospital air ambulance transport; the air transport of a patient from one hospital to another may be covered if the medical appropriateness criteria are met - that is, transportation by ground ambulance would endanger the beneficiary’s health and the transferring hospital does not have adequate

facilities to provide the medical services needed by the patient.)

5. **Local** - Per Pub. 100-02, chapter 10, section 10.3, as a general rule, only local transportation by ambulance is covered, and therefore, only mileage to the nearest appropriate facility equipped to treat the patient is covered.

6. **Part A** - For information on the Part A intermediary's processing of claims for ambulance services furnished under arrangements by participating hospitals, SNFs, and HHAs, see Pub. 100-02, chapter 10, section 10.1.4.

7. **Air Ambulance and Acute Care Hospitals** - As stated in Pub. 100-02, chapter 10, section 10.4.5, air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office, or a beneficiary's home.

For additional information on ambulance services, refer to:

- Section 1834(l) of the Social Security Act
- 42CFR410.40, 410.41, and 414.605.
- Pub. 100-02, chapter 10
- Pub. 100-04, chapter 15

4.2.8 – Intensive Cardiac Rehabilitation (ICR)

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

A. General Background Information

Effective January 1, 2010, Medicare Part B covers Intensive Cardiac Rehabilitation (ICR) program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.

The ICR programs must be approved by CMS through the national coverage determination (NCD) process and must meet certain criteria for approval. Individual sites wishing to provide ICR services via an approved ICR program must enroll with their local Medicare contractor or MAC as an ICR program supplier.

B. ICR Enrollment

In order to enroll as an ICR site, a supplier must complete a Form CMS-855B, with the supplier type of "Other" selected. Contractors shall verify that the ICR program is approved by CMS through the NCD process. A list of approved ICR programs will be identified through the NCD listings, the CMS Web site and the Federal Register. Contractors shall use one of these options to verify that the ICR program has met CMS approval.

The ICR suppliers shall be enrolled using specialty code 31. ICR suppliers must separately enroll each of their practice locations. Therefore, each enrolling ICR supplier can only have one practice location on its CMS-855B enrollment application and shall receive its own PTAN.

Contractors shall only accept and process reassignments (855R's) to ICR suppliers for physicians defined in 1861(r)(1) of the Act.

C. Additional Information

For more information on ICR suppliers, refer to:

- 42 CFR §410.49;
- Pub. 100-04, chapter 32, sections 140.2.2 – 140.2.2.6 (Medicare Claims Processing Manual); and

Pub. 100-02, chapter 15, sections 232 (Medicare Benefit Policy Manual)

15.4.3 - Medicare Advantage and Other Managed Care Organizations

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Medicare Advantage (MA) and other managed care organizations (MCOs) are allowed to bill Part B fee-for-service under certain situations. Such fee-for-service claims would include services provided to a beneficiary under the following situations: (1) the beneficiary has enrolled but their enrollment is not yet effective; (2) services provided by an attending physician or services unrelated to a terminal illness furnished to an enrollee who has elected hospice benefits; and (3) services furnished to an enrollee, but which are excluded under Section 1852(a)(5) of the Social Security Act from the MA/MCO contract.

NOTE: Specialty code 88 should be used.

15.4.4 - Individual Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

This section furnishes background information on certain types of non-physician

practitioners (NPPs). While Medicare has established Federal standards governing these supplier types, these practitioners must also comply with all applicable State and local laws as a precondition of enrollment.

The qualifications listed below for each NPP type – whether they were quoted from the applicable regulation or the appropriate manual instruction – represent current CMS policy.

15.4.4.1 - Anesthesiology Assistants
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-04, chapter 12, section 140.1, an anesthesiology assistant is a person who:

- Is permitted by State law to administer anesthesia; and

- Has successfully completed a 6-year program for anesthesiology assistants, of which 2 years consists of specialized academic and clinical training in anesthesia.

For more information on anesthesiology assistants, refer to:

- Section 1861(bb)(2) of the Social Security Act

- 42 CFR §410.69(b)

- Pub. 100-04, chapter 12, sections 140 – 140.4.4 (Claims Processing Manual)

15.4.4.2 - Audiologists
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42 CFR §440.110(c)(3), a "qualified audiologist" is an individual who:

- Has a master's or doctoral degree in audiology; and

- Is licensed as an audiologist by the State in which the individual furnishes such services and that State's requirements meet or exceed those in 42 CFR §440.110(c)(3)(ii)(A) or 42 CFR §440.110(c)(3)(ii)(B) (both of which are identified below).

If the person: (1) furnishes audiology services in a State that does not license audiologists, or (2) is exempted from State licensure based on practice in a specific institution or setting, the person must meet one of the following conditions:

- Have a Certificate of Clinical Competence in Audiology granted by the American Speech-Language-Hearing Association. (42 CFR §440.110(c)(3)(ii)(A))

OR

- Successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); and

- Performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and

- Successfully completed a national examination in audiology approved by the Secretary. (42 CFR §440.110(c)(3)(ii)(B))

Thus, if the individual does not have a State license for either of the reasons stated in 42 CFR §440.110(c)(3)(ii), the person must meet the certification requirement in 42 CFR §440.110(c)(3)(ii)(A), OR all three of the criteria listed in 42 CFR §440.110(c)(3)(ii)(B), in order to be eligible to enroll in Medicare.

For more information on audiologists, refer to:

- Section 1861(ll)(3)(B) of the Social Security Act

- Pub. 100-02, chapter 15, sections 80.3 and 80.3.1(Benefit Policy Manual)

15.4.4.3 - Certified Nurse-Midwives

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-02, chapter 15, section 180, a certified nurse-midwife must:

(1) Be currently licensed to practice in the State as a registered professional nurse; and

(2) Meet one of the following requirements:

a. Be legally authorized under State law or regulations to practice as a nurse-midwife and have completed a program of study and clinical experience for nurse-midwives, as specified by the State; OR

b. If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, the individual must:

1. Be currently certified as a nurse-midwife by the American College of Nurse-Midwives; or

2. Have satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives; or

3. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

All certified nurse-midwives, therefore, must: (1) be State-licensed as a registered nurse in the State in which the person seeks to practice as a nurse-midwife, (2) be legally authorized by the State to practice as a nurse-midwife, and (3) have completed a State-specified program of study and clinical experience for nurse-midwives. If the State does not specify such a program of study and clinical experience, the individual must meet one of the three criteria in 2(b) above.

For more information on certified nurse midwives, refer to:

- Section 1861(gg) of the Social Security Act
- 42 CFR §410.77
- Pub. 100-04, chapter 12, section 130 – 130.2 (Claims Processing Manual)

15.4.4.4 - Certified Registered Nurse Anesthetists (CRNAs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per 42 CFR 410.69(b), a certified registered nurse anesthetist means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to non-physician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) and within 24 months after that graduation meets the requirements of paragraph (4)(i).

For more information on CRNAs, refer to:

- Section 1861(bb) of the Social Security Act;
- 42 CFR §410.69(b); and
- Pub. 100-04, chapter 12, sections 140 through 140.4.4 (Claims Processing Manual).

15.4.4.5 - Clinical Nurse Specialists (CNS)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per Pub. 100-02, chapter 15, section 210, a clinical nurse specialist must meet all of the following requirements:

- Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with State law.
- Have a master's degree in a defined clinical area of nursing from an accredited educational institution. (Effective January 1, 2009, a doctor of nursing practice (DNP) doctoral degree will also meet this educational requirement.)
- Be certified as a clinical nurse specialist by a recognized national certifying body that has established standards for CNSs.

The following organizations are recognized national certifying bodies for CNSs at the advanced practice level:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

Under 42 CFR §410.76(c)(3), clinical nurse specialist services are covered only if, among other things, the CNS performed them while working in collaboration with a physician. Collaboration is a process in which a CNS works with one or more physicians to deliver health care services within the scope of the CNS's professional expertise, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on clinical nurse specialists, refer to:

- 42 CFR §410.76
- Pub. 100-02, chapter 15, section 210 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)

15.4.4.6 - Clinical Psychologists

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42CFR §410.71(d), to qualify as a clinical psychologist a practitioner must meet the following requirements:

- Hold a doctoral degree in psychology; and

- Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

A clinical psychologist must agree to meet the consultation requirements of 42 CFR §410.71(e)(1) through (e)(3). Under 42 CFR §410.71(e), the practitioner's signature on the Form CMS-855I indicates his or her agreement.

For more information on clinical psychologists, refer to:

- Pub. 100-04, chapter 12, sections 170 (Claims Processing Manual)

- Pub. 100-02, chapter 15, section 160 (Benefit Policy Manual).

15.4.4.7 - Clinical Social Workers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Under 42 CFR §410.73(a), to qualify as a clinical social worker a practitioner must meet the following requirements:

1. Possesses a master's or doctor's degree in social work;

2. After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

3. Either is licensed or certified as a clinical social worker by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a clinical social worker—

a. Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and

b. Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting, such as a hospital, SNF, or clinic.

For more information on clinical social workers, refer to:

- Section 1861(hh) of the Social Security Act
- Pub. 100-02, chapter 15, section 170 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, section 150 (Claims Processing Manual)

15.4.4.8 - Nurse Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Effective January 1, 2009, in order to bill Medicare a nurse practitioner must, as stated in 42 CFR §410.75(b), be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

(i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(ii) Possess a master’s degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in (1)(i) above.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

As stated in Pub. 100-02, chapter 15, section 200, the following organizations are

recognized national certifying bodies for NPs at the advanced practice level:

- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

In addition, under 42 CFR §410.75(c)(3) nurse practitioner services are covered only if, among other things, the nurse practitioner performed them while working in collaboration with a physician. Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the nurse practitioner's professional expertise, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished.

For more information on nurse practitioners, refer to:

- Pub. 100-02, chapter 15, section 200 (Benefit Policy Manual)
- Pub. 100-04, chapter 12, sections 120 and 120.1 (Claims Processing Manual)
- 42 CFR §410.150(b)(16)

15.4.4.9 - Occupational and Physical Therapists in Private Practice
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A. Occupational Therapists (OTs)

As stated in Pub. 100-02, chapter 15, section 230.2(B), a qualified occupational therapist for program coverage purposes is an individual who meets one of the

following requirements:

- Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education of the American Medical Association and the American Occupational Therapy Association;

- Is eligible for the National Registration Examination of the American Occupational Therapy Association; or

- Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

B. Physical Therapists (PTs)

As stated in Pub. 100-02, chapter 15, section 230.1(B), a qualified physical therapist for program coverage purposes is a person who is licensed as a physical therapist by the state in which he or she is practicing and meets one of the following requirements:

- Has graduated from a physical therapy curriculum approved by (1) the American Physical Therapy Association, or by (2) the Committee on Allied Health Education and Accreditation of the American Medical Association, or (3) Council on Medical Education of the American Medical Association, and the American Physical Therapy Association; or

- Prior to January 1, 1966, (1) was admitted to membership by the American Physical Therapy Association, or (2) was admitted to registration by the American Registry of Physical Therapists, or (3) has graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education; or

- Has 2 years of appropriate experience as a physical therapist and has achieved a satisfactory grade on a proficiency examination conducted, approved or sponsored by the Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking qualification as a physical therapist after December 31, 1977; or

- Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

- If trained outside the United States, (1) was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for

Physical Therapy, (2) meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

For more information on physical and occupational therapists, refer to:

- 42 CFR §410.59(c) (occupational therapists)
- 42 CFR §410.60(c) (physical therapists)
- Pub. 100-02, chapter 15, sections 230.2 and 230.4 (Benefit Policy Manual) (occupational therapists)
- Pub. 100-02, chapter 15, sections 230.1 and 230.4 (Benefit Policy Manual) (physical therapists)

15.4.4.10 - Physicians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As described in §1861(r)(1) of the Social Security Act and in 42 CFR §410.20(b), a physician must be legally authorized to practice medicine by the State in which he/she performs such services in order to enroll in the Medicare program and to retain Medicare billing privileges. Such individuals include:

1. Doctors of:

- Medicine or osteopathy
- Dental surgery or dental medicine
- Podiatric medicine
- Optometry

2. A chiropractor who meets the qualifications specified in 42 CFR §410.22

For information on physician billing, refer to Pub. 100-04, chapter 12. In addition, refer to Pub. 100-04, chapter 19, section 40.1.2, for special licensure rules regarding practitioners who work in or reassign benefits to hospitals or freestanding ambulatory care clinics operated by the IHS or by an Indian tribe or tribal organization.

15.4.4.11 - Physician Assistants (PAs)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-02, chapter 15, section 190, a physician assistant (PA) must meet the following Medicare requirements:

1. Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health

Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA); or

2. Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and

3. Be licensed by the State to practice as a physician assistant.

As indicated in Pub. 100-02, chapter 15, section 190(D):

- Payment for the PA's services may only be made to the PA's employer, not to the PA himself/herself. In other words, the PA cannot individually enroll in Medicare and receive direct payment for his or her services. This also means that the PA does not reassign his or her benefits to the employer, since the employer must receive direct payment anyway.

- The PA's employer can be either an individual or an organization. If the employer is a professional corporation or other duly qualified legal entity (e.g., LLC, LLP) in a State that permits PA ownership in the entity (e.g., as a stockholder, member), the entity may bill for PA services even if a PA is a stockholder or officer of the entity – so long as the entity is eligible to enroll as a provider or supplier in the Medicare program. PAs may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to, sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Moreover, leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.

For more information on physician assistants, refer to:

- 42 CFR §410.74

- 42 CFR §410.150(b)(15)

- Pub. 100-04, chapter 12, sections 110 through 110.3 (Claims Processing Manual)

15.4.4.12 - Psychologists Practicing Independently

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

As stated in Pub. 100-02, chapter 15, section 80.2, a psychologist practices independently when:

- They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;

- The persons they treat are their own patients;

- They have the right to bill directly, collect and retain the fee for their services; and

- The psychologist is State-licensed or certified.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:

- The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and

- The psychologist conducts a private practice (i.e., services are rendered to patients from outside the institution as well as to institutional patients).

The key distinction between independently practicing psychologists and clinical psychologists is that the latter requires a doctoral degree and has certain consultation requirements.

For more information on independently practicing psychologists, refer to:

- Pub. 100-04, chapter 12, sections 160 and 160.1 (Claims Processing Manual)

15.4.4.13 - Registered Dietitians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Per 42 CFR §410.134, a registered dietitian (or nutrition professional) means an individual who, on or after December 22, 2000:

1. Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose;

2. Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

3. Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian"" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (A) and (B) above.

There are two caveats to these requirements:

- A dietitian or nutritionist licensed or certified in a State as of December 21, 2000, is not required to meet the requirements of A and B above.

- A registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of A and B above.

For more information on registered dietitians, refer to:

- Sections 1861(vv) of the Social Security Act

- 42 CFR §410.130 through §410.134

15.4.4.14 – Speech Language Pathologists in Private Practice

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Effective July 1, 2009, in order to qualify as an outpatient speech-language pathologist in private practice, an individual must, under, meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology as an individual, in one of the following practice types:

(A) An unincorporated solo practice.

(B) An unincorporated partnership or unincorporated group practice.

(C) An unincorporated solo practice, partnership, or group practice, or a professional corporation or other incorporated speech-language pathology practice.

(D) An employee of a physician group.

(E) An employee of a group that is not a professional corporation.

For more information on speech language pathologists in private practice, refer to: Pub. 100-02, chapter 15, section 230.

15.4.5 - Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Since carriers make payments for implantable prosthetics and DME to hospitals, physicians or ASCs, carriers shall not enroll manufacturers of implantable or non-implantable and prosthetics DME into the Medicare program. Manufacturers of non-implantable prosthetics and DME and replacement parts and supplies for prosthetic implants and surgically implantable DME may enroll in the Medicare program as a supplier with the NSC if they meet the definition of a supplier as well as the requirements set forth in 42 CFR § 424.57.

15.4.6 - Other Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.4.6.1 - Diabetes Self-Management Training (DSMT)

(Rev. 365, Issued: 01-28-11, Effective: 03-30-09, Implementation: 04-29-11)

General Background Information

The DSMT is not a separately recognized provider type like a physician or nurse practitioner. A person or entity cannot enroll in Medicare for the sole purpose of performing DSMT. Rather, DSMT is merely an extra service that a currently-enrolled provider or supplier can bill for, assuming it meets all of the necessary DSMT requirements.

All DSMT programs must be accredited as meeting quality standards by a CMS-approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association (ADA), *American Association of Diabetes Educators* and the Indian Health Service as approved national accreditation organizations. A Medicare-enrolled provider or non-DMEPOS supplier that wishes to bill for DSMT may simply submit the ADA certificate to its contractor. No Form CMS-855 paperwork is required, unless the provider or supplier is not in PECOS, in which case - per section 7.1.1 of *Pub. 100-08, Medicare Program Integrity Manual, Chapter 10* – a complete Form CMS-855 application is required.

If the supplier is exclusively a DMEPOS supplier, it must complete and submit a Form CMS-855B application to its local carrier. This is because DMERCs do not pay DSMT claims, but carriers can. Thus, the DMEPOS supplier must separately enroll with its carrier, even if it has already completed a Form CMS-855S. If a carrier receives an application from a DMEPOS supplier that would like to bill for DMST, it shall verify with the National Supplier Clearinghouse that the applicant is currently enrolled and eligible to bill the Medicare program.

For more information on DSMT, refer to:

- Section 1861(qq) of the Social Security Act
- 42 CFR Part 410 (subpart H)

- Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, sections 300 – 300.5.1.

15.4.6.2 - Mass Immunizers Who Roster Bill

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

An entity or individual who wishes to furnish mass immunization services, but may not otherwise qualify as a Medicare provider, may be eligible to enroll as a "Mass Immunizer" via the Form CMS-855I (individuals) or the Form CMS-855B (entities). Such providers, among other things, must meet the following requirements:

- They may not bill Medicare for any services other than pneumococcal pneumonia vaccines (PPVs), influenza virus vaccines, and their administration.

- They must submit claims through the roster billing process.

- All personnel who administer the shots must meet all applicable State and local licensure or certification requirements.

The roster billing process was developed to enable Medicare beneficiaries to participate in mass PPV and influenza virus vaccination programs offered by public health clinics and other organizations and persons who give the vaccine to a group of beneficiaries at sites such as clinics, shopping malls, grocery stores, senior citizen homes, and health fairs.

For more information on mass immunization roster billing, refer to:

- Pub. 100-02, chapter 15, section 50.4.4.2 (Benefit Policy Manual)

    - Pub. 100-04, chapter 18, sections 10 through 10.3.2.3 (Claims Processing Manual)

NOTE: Section 10.3.1 outlines the requirements for submitting roster bills.

15.4.7 - Medicaid State Agencies

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Only recognized providers and suppliers of services that have a National Provider Identifier (NPI) number can enroll in the Medicare program. Medicaid State agencies are not eligible to apply for an NPI. As such, Medicaid State agencies are not eligible to enroll in the Medicare program and shall not be issued billing privileges or be allowed to maintain billing privileges.

If a Medicaid State agency is enrolled or is seeking enrollment as a provider or supplier in the Medicare program, the fee-for-service contractor shall deny or revoke Medicare billing privileges. In denying a Medicaid State agency's application to enroll in the

Medicare program, fee-for-service contractors shall use denial reason five (5) found in section 6.2 of this chapter. In revoking a Medicaid State agency billing privileges, a fee-for-service contractor shall use revocation reason three (3) found in section 13 of this chapter. The revocation letter should indicate that the revocation will be effective 30 days after the date of the revocation letter

15.4.8 - Suppliers Not Eligible to Participate

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Below is a list of suppliers who frequently attempt to enroll in the Medicare Program but are not eligible to do so.

If the contractor receives an enrollment application from any of the following individuals or organizations below, the contractor shall deny the application without development.

- Acupuncturist
- Assisted Living Facilities
- Birthing Centers
- Certified Alcohol and Drug Counselor
- Certified Social Worker
- Drug and Alcohol Rehabilitation Counselor
- Hearing Aid Center/Dealer
- Licensed Alcoholic and Drug Counselor
- Licensed Massage Therapist (LMT)
- Licensed Practical Nurse (LPN)
- Licensed Professional Counselor
- Marriage Family Therapist (MFT)
- Masters of Social Work
- Mental Health Counselor
- National Certified Counselor
- Occupational Therapist Assistant
- Physical Therapist Assistant
- Registered Nurse
- Speech and Hearing Center
- Substance Abuse Facility

15.5 – Advanced Diagnostic Imaging
(Rev.)

15.5.1 - Jurisdictional Issues
(Rev. 363, Issued: 01-14-11, Effective: 02-15-11, Implementation: 02-15-11)

A. Audit and Claims Intermediaries

For purposes of enrollment, there are generally two categories of intermediaries: audit intermediaries and claims intermediaries. The audit intermediary enrolls the provider, conducts audits, etc. The claims intermediary pays the provider's claims. In most cases, the provider's audit intermediary and claims intermediary will be the same. On occasion, however, they will be different; this often happens with provider-based entities, whereby the provider's enrollment application will be processed by the parent provider's intermediary (audit intermediary) and its claims will be paid by a different intermediary (claims intermediary).

In situations where the audit and claims intermediaries differ, the audit intermediary shall process all changes of information, including all EFT changes. The audit intermediary shall notify the applicant during the initial enrollment process that all future changes of information must be sent to the audit intermediary, not the claims intermediary. (Quite often, a provider will submit an EFT change request to the claims intermediary because the latter processes the provider's claims.) If the provider inadvertently sends a change of information request (or, for that matter, an initial enrollment) to the claims intermediary, the latter shall return the application per section 15.8.1 of this chapter.

Once the audit intermediary finishes processing the initial enrollment application, change of information, voluntary termination, or any other CMS-855 transaction, it shall e-mail a notification of the applicable CMS-855 transaction to the claims intermediary that information has been updated in PECOS. Pertinent identifying information such as the Provider Name, CCN, NPI, and ERID should be included on the e-mail notification. Any supporting documentation that may contain Personal Health Information (PHI) or Personally Identifiable Information (PII) such as Electronic Funds Transfer (EFT) may still be faxed to the claims intermediary.

Upon receipt of the e-mail notification, the claims intermediary shall be responsible for accessing PECOS and reviewing the enrollment record ID to see what has changed and update its records accordingly.

The audit intermediary shall be responsible for keeping the original copies on the CMS 855 paperwork and supporting documentation.

Moreover, in situations where the audit intermediary is different from the claims intermediary, the audit intermediary shall e-mail a copy of all tie-in and tie-out notices it receives to the claims intermediary. For instance, if the audit intermediary receives a

tie-in notice signifying that a provider's request for Medicare participation has been approved, the audit intermediary shall send an e-mail copy to the claims intermediary. This is to ensure that the claims intermediary is fully aware of the RO's action, as some ROs may only send copies of tie-in and tie-out notices to the audit intermediary. If the audit intermediary chooses, it can simply contact the claims intermediary by phone or e-mail and ask if the latter received the tie-in notice.

Again, it is imperative that audit and claims intermediaries effectively communicate and coordinate with each other in all payment-related and program integrity matters involving the provider.

B. Provider Nomination

With respect to issues regarding provider nomination and changes of intermediaries, the contractor shall adhere to the instructions in Pub. 100-04, chapter 1, sections 20 through 20.5.1.

If an intermediary receives a request from a provider to change its existing intermediary, it shall refer the provider to the RO contact person responsible for intermediary assignments.

6 - Timeliness and Accuracy Standards

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Sections 6.1 through 6.3 of this chapter address the timeliness and accuracy standards applicable to the processing of CMS-855 applications. Even though the provisions of 42 CFR § 405.874(h) contain processing timeframes that are longer than those in sections 6.1 through 6.3, the contractor shall adhere to the standards specified in sections 6.1 through 6.3.

The processing of an application generally includes, but is not limited to, the following activities:

- Receipt of the application in the contractor's mailroom and forwarding it to the appropriate office for review;

- Prescreening the application in accordance with section 7.1 of this chapter;

- Creating an L & T record and an enrollment record in PECOS;

- Verification of the application in accordance with sections 8.1 through 8.7.1 of this chapter;

- Requesting and receiving clarifying information in accordance with section 8.3 of this chapter;

- Site visit (if necessary);

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary) for approval or denial.

6.1 – Standards for Initial Applications

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

For purposes of sections 6.1.1 through 6.1.4 of this chapter, the term "initial applications" also includes:

1. CHOW, acquisition/merger, and consolidation applications submitted by the new owner;

2. "Complete" CMS-855 applications submitted by enrolled providers: (a) voluntarily, (b) as part of any change request if the provider does not have an established enrollment record in PECOS, (c) as part of a reactivation, or (d) as part of a revalidation. (See section 13.1.1 of this manual for more information on the processing of "complete" applications.)

6.1.1 - Paper Applications - Timeliness

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

For purposes of sections 6.1.1.2 though 6.1.1.4 below, the term "development" has the same general meaning as that used in section 8.3 of this chapter – specifically, the need to contact the supplier for additional information. (A prescreening letter to the provider is considered to be the first developmental request.)

6.1.1.1 – CMS-855A Applications

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 80 percent of CMS-855A initial applications within 60 calendar days of receipt, process 90 percent of CMS-855A initial applications within 120 calendar days of receipt, and process 99 percent of CMS-855A initial applications within 180 calendar days of receipt.

6.1.1.2 – CMS-855I Applications

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 80 percent of all initial CMS-855I applications where no contractor development is needed within 60 calendar days of receipt, and 95 percent of such applications within 90 calendar days of receipt.

The contractor shall process 80 percent of all initial CMS-855I applications where one developmental request is made by the contractor within 90 calendar days of receipt, 90 percent of such applications within 120 calendar days of receipt, and 95 percent of such

applications within 180 calendar days of receipt.

The contractor shall process 70 percent of all initial CMS-855I applications where at least two developmental requests are made by the contractor within 90 calendar days of receipt, 80 percent of such applications within 120 calendar days of receipt, and 90 percent of such applications within 180 calendar days of receipt.

6.1.1.3 – CMS-855B Applications Submitted by Suppliers Other Than IDTFs

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

(This section 6.1.1.3 applies only to initial CMS-855B applications submitted by suppliers other than IDTFs.)

The contractor shall process 80 percent of all initial CMS-855B applications where no contractor development is needed within 60 calendar days of receipt, and 95 percent of such applications within 90 calendar days of receipt.

The contractor shall process 80 percent of all initial CMS-855B applications where one developmental request is made by the contractor within 90 calendar days of receipt, 90 percent of such applications within 120 calendar days of receipt, and 95 percent of such applications within 180 calendar days of receipt.

The contractor shall process 70 percent of all initial CMS-855B applications where at least two developmental requests are made by the contractor within 90 calendar days of receipt, 80 percent of such applications within 120 calendar days of receipt, and 90 percent of such applications within 180 calendar days of receipt.

6.1.1.4 – CMS-855B Applications Submitted by IDTFs

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 70 percent of all initial IDTF CMS-855B applications where no contractor development is needed within 90 calendar days of receipt, 80 percent of such applications within 120 calendar days of receipt, and 95 percent of such applications within 180 calendar days of receipt.

The contractor shall process 65 percent of all initial IDTF CMS-855B applications where one developmental request is made by the contractor within 90 calendar days of receipt, 75 percent of such applications within 120 calendar days of receipt, and 90 percent of such applications within 180 calendar days of receipt.

The contractor shall process 60 percent of all initial IDTF CMS-855B applications where two or more developmental requests are made by the contractor within 90 calendar days of receipt, 70 percent of such applications within 120 calendar days of receipt, and 80 percent of such applications within 180 calendar days of receipt.

6.1.2 - Paper Applications – Accuracy
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 98 percent of paper CMS-855 initial applications in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 6.1.1 above) and all other applicable CMS directives.

6.1.3 - Web-Based Applications - Timeliness
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 90 percent of CMS-855 Web-based initial applications within 45 calendar days of receipt, process 95 percent of CMS-855 Web-based initial applications within 60 calendar days of receipt, and process 99 percent of CMS-855 Web-based initial applications within 90 calendar days of receipt. This process generally includes, but is not limited to:

Receipt of the provider's certification statement in the contractor's mailroom and forwarding it to the appropriate office for review;

- Verification of the application in accordance with sections 8.1 through 8.6 of this manual;

- Requesting and receiving clarifying information in accordance with section 8.3 of this manual;

- Supplier site visit (if necessary);

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary) for approval or denial.

6.1.4 - Web-Based Applications - Accuracy
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 98 percent of CMS-855 Web-based initial applications in full accordance with all of the instructions in chapter 15 (with the exception of the timeliness standards identified in section 6.1.3 above) and all other applicable CMS directives.

6.2 – Standards for Changes of Information
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

For purposes of timeliness, the term "changes of information" also includes:

1. CHOW, acquisition/merger, and consolidation applications submitted by the old owner;

2. CMS-588 changes submitted without a need for an accompanying complete CMS-855 application;

3. CMS-855R applications submitted independently (i.e., without being part of a CMS-855I or CMS-855B package); and

4. CMS-855 voluntary terminations

6.2.1 - Paper Applications - Timeliness

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 80 percent of paper CMS-855 changes of information within 60 calendar days of receipt, process 90 percent of paper CMS-855 changes of information within 90 calendar days of receipt, and process 95 percent of paper CMS-855 changes of information within 120 calendar days of receipt. This process generally includes, but is not limited to, the following activities:

- Receipt of the change request in the contractor's mailroom and forwarding it to the appropriate office for review;

- Prescreening the change request in accordance with section 7.1 of this manual;

- Creating an L & T record and, if applicable, tying it to an enrollment record in PECOS;

- Verification of the change request in accordance with sections 8.1 through 8.6 of this manual, as well as the applicable instructions in sections 13.1 and 13.2 of this manual;

- Requesting and receiving clarifying information in accordance with section 8.3 of this manual;

- Supplier site visit (if necessary);

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary) for approval or denial.

6.2.2 - Paper Applications - Accuracy

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 98 percent of paper CMS-855 changes of information in full accordance with all of the instructions in chapter 10 (with the exception of the timeliness standards identified in section 6.2.1 above) and all other applicable CMS directives.

6.2.3 - Web-Based Applications - Timeliness
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 90 percent of CMS-855 Web-based changes of information applications within 45 calendar days of receipt, process 95 percent of CMS-855 Web-based changes of information within 60 calendar days of receipt, and process 99 percent of CMS-855 Web-based changes of information within 90 calendar days of receipt. This process generally includes, but is not limited to:

- Receipt of the provider's certification statement in the contractor's mailroom and forwarding it to the appropriate office for review;

- Verification of the change request in accordance with sections 8.1 through 8.6 of this manual, as well as the applicable instructions in sections 13.1 and 13.2 of this manual;

- Requesting and receiving clarifying information in accordance with section 8.3 of this manual;

- Supplier site visit (if necessary);

- Formal notification of the contractor's decision or recommendation (and providing the appropriate appeal rights, as necessary) for approval or denial.

6.2.4 - Web-Based Applications – Accuracy
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The contractor shall process 98 percent of CMS-855 Web-based change of information applications in full accordance with all of the instructions in chapter 15 (with the exception of the timeliness standards identified in section 6.2.3 above) and all other applicable CMS directives.

6.3 - General Timeliness Principles
(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Unless stated otherwise, the principles discussed below apply to all applications discussed in sections 6.9 through 6.2.4 above (e.g., CHOW applications submitted by old and new owners, CMS-588 forms).

A. Clock Stoppages

The processing time clocks identified in sections 6.1 and 6.2 of this manual cannot be stopped or suspended for any reason. This includes, but is not limited to, the following situations:

- Referring an application to the OIG or the Payment Safeguard Contractor (PSC);

- Waiting for the final sales agreement (e.g., CHOW, acquisition/merger);

- Waiting for the RO to make a provider-based, HHA capitalization, or CHOW determination;

- Referring a provider to the Social Security Administration (SSA) to resolve a discrepancy involving a social security number (SSN), as explained in section 4.2.1 of this manual.

- Contacting CO (e.g., DPSE) or an RO's survey/certification staff with a question regarding the application in question or CMS policy.

Despite the prohibition on clock stoppages and suspensions, the contractor should always document any delays by identifying when the referral to CMS, the OIG, etc., was made, the reason for the referral, and when a response was received. By doing so, the contractor will be able to furnish explanatory documentation to CMS should applicable time limits be exceeded. To illustrate, assume a contractor received an initial CMS-855B application on March 1. On March 30, the contractor sent an adverse legal action question to CMS, and received a reply on April 7. The processing time clock did not stop from March 31 to April 7. However, the contractor should document its files to explain that it forwarded the question to CMS, the dates involved, and the reason for the referral.

B. Calendar Days

Unless otherwise stated in this manual, all days in the processing time clock are "calendar" days, not "business days." If the 60th day (for initials) or 45th day (for changes of information) falls on a weekend or holiday, this is still the day by which the application must be processed. If the contractor is unable to finish processing the application until the next business day, however, it should document the file that the 60th day fell on a Saturday/Sunday/holiday and furnish any additional explanation as needed.

C. Date-Stamping

As a general rule, all incoming correspondence must be date-stamped on the date it was received in the contractor's mailroom. This includes, but is not limited to:

Any CMS-855 application, including initials, changes, CHOWs, etc. (The first page of the application must be date-stamped.)

- Letters from providers. (The first page of the letter must be date-stamped.)

- Supporting documentation, such as licenses, certifications, articles of incorporation, and billing agreements. (The first page of the document or the envelope must be date-stamped.)

- Data furnished by the provider (via mail or fax) per the contractor's request for additional information. (All submitted pages must be date-stamped. This is because many contractors interleaf the new/changed pages within the original application; hence, it is necessary to determine the sequence in which the application and the additional pages were received.)

The timeliness clocks discussed in sections 6.1 and 6.2 above start on the date the application/envelope is date-stamped in the contractor's mailroom, not when the application is date-stamped or received by the provider enrollment unit. As such, the date-stamping activities described in the aforementioned bullets must be performed in the contractor's mailroom. In cases where the mailroom staff fails to date-stamp a particular document, the provider enrollment unit may date-stamp the page in question. However, there shall not be long lapses between the time it was received in the mailroom and the time the provider enrollment unit date-stamped the pages.

In addition, and unless stated otherwise in this manual or other CMS directive, all incoming enrollment applications (including change requests) must be submitted via mail.

D. When the Processing Cycle Ends

For: (1) fiscal intermediaries, and (2) carriers processing ASC or portable x-ray applications, the processing cycle ends on the date the contractor sends its recommendation for approval or denial to the State agency. In situations involving a change request that does not require a recommendation (i.e., it need not be forwarded to and approved by the State or RO), the cycle ends on the date the contractor sends notification to the provider that the change has been processed. If notification to the provider is made via telephone, the cycle ends on the date the telephone call is made (e.g., the date the voice mail message is left).

For carriers processing applications other than those from ASCs and portable x-ray suppliers, the processing cycle ends on the date the carrier sends its approval/denial letter to the supplier. For change request approval/denial notifications made via telephone, the cycle ends on the date the telephone call is made (e.g., the date the voice mail message is left).

For any application that is rejected per section 7.1 or 8.3 of this manual, the processing time clock ends on the date the contractor sends notification to the provider that the application has been rejected.

E. PECOS

Unless stated otherwise in this manual, the contractor must create an L & T record in PECOS no later than 15 calendar days after its receipt of the provider's application in the contractor's mailroom. Moreover, the contractor must establish a complete enrollment record in PECOS – if applicable - prior to its approval or denial of (or recommendation of approval or denial of) the provider's application; to the maximum extent possible, the contractor shall establish the enrollment record at one time, rather than on a piecemeal basis.

The L & T and enrollment record requirements in the previous paragraph apply to all applications identified in sections 6.1 and 6.2 above (e.g., reassignments, CHOW applications submitted by old and new owners).

In situations where the contractor cannot create an L & T record within 15 days due to missing information (e.g., no NPI was furnished), the contractor shall document the provider file accordingly.

15.7 – Application Review and Verification Activities

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Unless stated otherwise in this manual, the instructions in sections 7 through 7.3 apply to the CMS-855A, the CMS-855B and the CMS-855I. These instructions are in addition to, and not in lieu of, all other instructions in this manual.

15.7.1 – General Verification Principles

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Unless stated otherwise in this manual, the contractor shall comply with the following principles when processing CMS-855 enrollment applications:

- **Completeness:** The contractor shall ensure that the provider completed all required data elements on the CMS-855 (including all effective dates) and that all supporting documentation has been furnished. The contractor shall also ensure that the provider completed the application in accordance with the instructions on the CMS-855 form. (Note that the instructions on the CMS-855 shall be read and applied in addition to, and not in lieu of, the instructions in this manual.)

- **Written Data Elements:** Unless stated otherwise in this manual or other CMS directive, the provider shall complete all required data elements on the CMS-855 via the application itself. The contractor shall not accept any required information captured on the CMS-855 via telephone, letterhead, e-mail, etc., regardless of the relative materiality of the data element in question.

- **Validation:** The contractor shall verify and validate all information furnished by the provider on the CMS-855. (See section 7.2 below for more information.)

- **Photocopying Pages -** The contractor may accept photocopied pages in any CMS-855 application it receives so long as the application contains an original signature. For example, suppose a corporation wants to enroll five medical clinics it owns. The section 5 data on the CMS-855B is exactly the same for all five clinics. The contractor may accept photocopied section 5 pages for these providers. However, original signatures must be furnished in section 15 of each application.

- **White-Out & Highlighting -** The contractor shall not write on, or highlight any part of, the original CMS-855 application or any supplementary pages the applicant submits. Provider usage of white-out is acceptable, although the contractor should contact the applicant to resolve any ambiguities. In addition, the contractor must determine whether the amount of white-out used on a particular application is within reason. For instance, if an entire application page is whited-out, the contractor should request that the page be resubmitted.

15.7.2 – Verification of Data

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The general purpose of the verification process is to determine if any of the data furnished on the CMS-855 is incorrect. The contractor may begin the verification process at any time, including during the prescreening phase.

A. Concurrent Reviews

If the contractor receives multiple CMS-855s for related entities, it can perform concurrent reviews of similar data. For instance, suppose a chain home office submits initial CMS-855A applications for four of its chain providers. The ownership information (sections 5 and 6) and chain home office data (section 7) is the same for all four providers. The contractor need only verify the ownership and home office data once; it need not do it four times – once for each provider. However, the contractor shall document in each provider's file that a single verification check was made for all four applications.

For purposes of this requirement: (1) there must be some sort of organizational, employment, or other business relationship between the entities, and (2) the applications must have been submitted simultaneously – or at least within a few weeks of each other. As an illustration, assume that Group Practice A submits an initial CMS-855B on January 1. Group Practice B submits one on October 1. Section 6 indicates that Joe Smith is a co-owner of both practices, though both entities have many other owners that are not similar. In this case, the contractor must verify Mr. Smith's data in both January and October. It cannot use the January verification and apply it to Group B's application because: (1) the applications were submitted nine months apart, and (2) there is no evidence that the entities are related. (On the other hand, a CMS-855I, CMS-855B, and CMS-855R enrollment package would probably meet the two criteria above.)

B. Mechanisms of Verification

Unless stated otherwise in this manual or in other CMS directives (e.g., JSMs), the contractor shall verify all data furnished on the CMS-855 via the most cost-effective method available. Such data includes, but is not limited to:

- Adverse legal history of the provider and all entities and persons listed in sections 5 and 6 of the CMS-855.

- For non-certified suppliers (e.g., physician clinics), all practice locations and phone numbers listed in section 4 of the CMS-855.

- Legal business names and employer identification numbers of all entities listed in sections 5, 7, 8, and 12 of the CMS-855.

Examples of verification techniques include:

- **Phone number of provider's practice location or billing agency -** Calling the number listed on the application directly; checking the Yellow Pages.

- **Provider's practice location -** Checking the Yellow Pages; conducting a site visit.

- **Provider's "doing business as" name –** Searching State Web sites

If the discrepancy is found between the information of the application and the data found during the verification process, the contractor shall contact the provider for clarification.

In addition:

- There may be instances where CMS directs contractors to verify certain data via the Medicare Exclusion Database and/or the GSA Excluded Parties List System. If a potential hit is found on the GSA List and the contractor needs to make a positive identity, it shall contact the agency that took the action for further information; based on this data, the contractor shall determine whether it is the same person. If a positive match still cannot be made, the contractor may approve the application.

- The contractor is not required to use the Fraud Investigation Database (FID) when processing incoming enrollment applications, including changes of information. If the contractor chooses to use the FID on a particular provider, owner, etc., and the person/entity appears on the FID, the contractor should continue to process the application. However, it should refer the matter to the PSC.

In some instances, a contractor may need to contact another Medicare contractor for information regarding the provider. The latter contractor shall respond to the former

contractor's request within three business days absent extenuating circumstances.

15.7.3 - Documentation
(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

To ensure that proper internal controls are maintained and that important information is recorded in case of potential litigation, the contractor shall maintain documentation as outlined in this section 7.3. CMS cannot stress enough how crucial it is for contractors to document their actions as carefully and thoroughly as possible.

Note that these requirements are in addition to, and not in lieu of, all other documentation or document maintenance requirements that CMS has mandated.

A. Written and Telephonic Communications

(For purposes of this section 7.3, "written correspondence" includes faxes and e-mails.)

The contractor shall:

- Retain copies of all written correspondence pertaining to the provider, regardless of whether the correspondence was initiated by the contractor, the provider, CMS, State officials, etc.

- Document when it sends written letters and faxes to providers. For instance, if the carrier crafts an approval letter to the supplier dated March 1 but sends it out on March 3, the contractor shall note this in the file.

- Document all referrals to CMS, the PSC, or the OIG.

- Document any and all actual or attempted telephonic or face-to-face contacts with the provider, any representative thereof, or any other person regarding a provider. This includes, but is not limited to, the following situations:

    - Telephoning a provider about its application. (Even if the provider official was unavailable and a voice mail message was left, this must be documented.)

    - Requesting information from the State or another contractor concerning the applicant or enrollee;

    - Contacting the PSC for an update concerning an application sent to them;

    - Phone calls from the provider;

    - Conducting a meeting at the contractor's headquarters/offices with officials from a hospital concerning problems with its application;

- Contacting CO or the RO's survey and certification staff – and receiving instructions there from - about a problem the contractor is having with an applicant or an existing provider;

- Contacting the provider's billing department with a question about the provider.

When documenting oral communications, the contractor shall indicate: (1) the time and date of the call or contact; (2) who initiated contact; (3) who was spoken with; and (4) what the conversation pertained to. Concerning the last requirement, the contractor need not write down every word that was said during the conversation. Rather, the documentation should merely be adequate to reflect the contents of the conversation. The documentation can be stored electronically, if the contractor can provide access within 24 hours upon request.

Note that the documentation requirements in this subsection (A) only apply to enrolled providers and to providers that have already submitted an enrollment application. In other words, these documentation requirements go into effect only after the provider submits an initial application. To illustrate, if a hospital contacts the contractor requesting information concerning how it should enroll in the Medicare program, this need not be documented because the hospital has not yet submitted an enrollment application.

If an application is returned per section 8.1 of this manual, the contractor shall document this. The manner of documentation lies within the contractor's discretion.

B. Verification of Data Elements

Once the contractor has completed its review of the CMS-855 (e.g., approved/denied application, approved change request), it shall provide a written statement asserting that it has: (1) verified all data elements on the application, and (2) reviewed all applicable names on the CMS-855 against Qualifier.net, the MED, and the GSA debarment list. The statement must be signed and dated. It can be drafted in any manner the contractor chooses so long as it certifies that the above-mentioned activities were completed. The record can be stored electronically.

For each person or entity that appeared on the MED or GSA lists, the contractor shall document the finding via a screen printout. In all other situations, the contractor is not encouraged to document their reviews via screen printouts. Simply using the verification statement described above is sufficient. Although the contractor has the discretion to use screen prints if it so chooses, the verification statement is still required.

15.7.4 - Tie-In Notices

(Rev. 372, Issued: 03-25-11, Effective: 10-01-10, Implementation: 04-25-11)

Although it may vary by RO, tie-in and tie-out notices are generally issued in the

following circumstances:

- Initial enrollment;
- CHOW;
- Acquisition/Merger;
- Consolidation;
- Addition or deletion of HHA branch, hospital unit, or OPT extension site;
- Voluntary and involuntary termination of billing numbers

As each RO may have different practices for issuing tie-in and tie-out notices, the intermediary should contact its RO to find out the specific circumstances in which such notices are issued.

This also applies to instances when the RO delegates the task of issuing tie-in or tie-out notices to the State agency. The intermediary may accept such notices from the State in lieu of those from the RO. However, the intermediary should first contact the applicable RO to confirm: (1) that the latter has indeed delegated this function to the State, and (2) the specific transactions (e.g., CHOWs, HHA branch additions) for which this function has been delegated.
In addition:

- **Review for Consistency** - When the contractor receives a tie-in notice or approval letter from the RO, it shall review its contents to ensure that the data on the notice/letter matches that on the CMS-855. If there are discrepancies (e.g., different legal business name, address), the contractor shall notify its DPSE liaison. It shall also contact the applicable RO to determine why the data is different.

- **Receipt of Tie-In When CMS-855A Not Completed** - If the contractor receives a tie-in notice from the RO but the provider never completed the necessary CMS-855A paperwork*, the contractor shall immediately contact the RO and apprise it of the situation. Then the contractor shall contact the provider and* have the provider complete and submit said paperwork. (This applies to initial applications, CHOWs, practice location additions, etc.)

Although SAs and accreditation organizations (AOs) are aware that, in accordance with Section 2003B of the State Operations Manual (SOM), they should not perform a survey of a new facility until the MAC/legacy FI/legacy carrier has provided notice that the information provided on the enrollment application has been verified and enrollment is being recommended, circumstances do occur when the sequence is reversed. When the survey occurs prior to the enrollment verification activities, we believe it is essential that the provider agreement or supplier approval date be based on the later date, i.e., the date the contractor determined that the enrollment application verification.

42 CFR 489.13 governs the determination of the effective date of a Medicare provider

agreement or supplier approval for health care facilities that are subject to survey and certification. §489.13 has been revised to make it clearer that the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met, and that such requirements include review and verification of an application to enroll in the Medicare program by CMS's legacy fiscal intermediary (FI), legacy carrier, or Medicare Administrative Contractor (MAC).

- **Creation of New L & T Record Unnecessary** - The intermediary is not required to create a new L & T record in PECOS when the tie-in notice comes in, as the existing record should not be in a final status and can therefore be modified. Simply changing the L & T status is sufficient.

15.7.5 – Special Program Integrity Procedures
(Rev.)

15.7.5.1 – Special Procedures for Physicians and Non-Physician Practitioners
(Rev.)

15.7.5.2 – Verification of Legalized Status
(Rev.)

15.8 – Initial Determinations and Other Administrative Actions
(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

15.8.1 – Returning the Application
(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

A. Immediate Returns

The contractor shall immediately return the enrollment application to the provider in the instances described below. This policy applies to all applications identified in sections 4.1 and 4.2 of this manual:

- There is no signature on the CMS-855 application or Internet-Based PECOS Certification Statement;

- The provider submits the outdated paper version of the paper CMS-855 application;

- The application contains a copied or stamped signature;

- The signature on the application is not dated;

- The CMS-855I application was signed by someone other than the individual practitioner applying for enrollment;

- The applicant failed to submit all of the forms needed to process a reassignment package within 15 calendar days of receipt (as described in section 5.4 of this manual);

- The applicant sent its CMS-855 to the wrong contractor (e.g., the application was sent to Carrier X instead of Carrier Y);

- The applicant completed the form in pencil;

- The applicant submitted the wrong application (e.g., a CMS-855B was submitted to a fiscal intermediary);

- If a Web-generated application is submitted, it does not appear to have been downloaded off of CMS's Web site;

- An old owner or new owner in a CHOW submitted its application more than 3 months prior to the anticipated date of the sale. (This only applies to fiscal intermediaries.)

- The application was faxed or e-mailed in;

- The contractor received the application more than 30 days prior to the effective date listed on the application. (This does not apply to certified providers, ASCs, or portable x-ray suppliers.);

- The contractor can confirm that the provider submitted a new enrollment application prior to the expiration of the time period in which the provider is entitled to appeal the denial of its previously submitted application;

- The contractor discovers or determines that the provider submitted a CMS-855 application for the sole purpose of enrolling in Medicaid; the only exception to this is when the provider is required to submit a Medicare cost report in order to participate in a State Medicaid program;

- The CMS-855 is not needed for the transaction in question. (A common example is an enrolled physician who wants to change his reassignment of benefits from one group to another group and submits a CMS 855I and a CMS 855R. As only the CMS 855R is needed, the CMS-855I shall be returned.);

- The CMS-588 was sent in as a stand-alone change of information request (i.e., it was not accompanied by a CMS-855) but was (1) unsigned, (2) undated, or (3) contained a copied, stamped, or faxed signature.

- The circumstances in sections 5.5.2.5, 5.5.2.5.1, or 5.6.2.1.2 of this manual apply.

The contractor need not request additional information in any of the scenarios described above. Thus, for instance, if the application was not signed, the contractor can return the application immediately.

NOTE: The difference between a "rejected" application and a "returned" application; the former is based on the provider's failure to respond to the contractor's request for missing or clarifying information. A "returned" application is considered a non-application.

For CMS-855A and CMS-855B applications, if the form is signed but it appears the person does not have the authority to do so, the contractor shall process the application normally and follow the instructions in sections 4.15 and 4.16 accordingly. Returning the application on this basis alone is not permitted.

B. Procedures for Returning the Application

If the contractor returns the application:

- It shall notify the provider via letter or e-mail that the application is being returned, the reason(s) for the return, and how to reapply.

- It shall <u>not</u> enter the application into PECOS. No L & T record shall be created.

- Any application resubmission must contain a brand new certification statement page containing a signature and date. The provider cannot simply add its signature to the original certification statement it submitted.

- Return all other documents submitted with the application (e.g., CMS-588, CMS-460).

C. EFT Agreements

A non-signature on the CMS-588 EFT form (assuming that it is submitted in conjunction with a CMS-855 initial application or change request) is not grounds for returning the entire application package. The contractor shall simply develop for the signature using the procedures cited in section 5.3 of this manual. However, the EFT form must contain an original signature when it is finally submitted. Faxed EFT agreements are not permitted. (This is an exception to the general rule in section 5.3 that contractors can receive additional or clarifying information via fax.) Once the provider submits an EFT agreement with an original signature, any additional or clarifying information the contractor needs with respect to that document can be submitted by the provider via fax. (The provider must still, of course, furnish a new signature when it adds the new information.)

15.8.2 – Application Rejections
(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

(This section 8.2 does not apply to the following individuals and organizations that are submitting an initial application, a change request, or a reassignment:

1. Physicians
2. Physician assistants
3. Nurse practitioners
4. Clinical nurse specialists
5. Certified registered nurse anesthetist
6. Certified nurse-midwife
7. Clinical social worker
8. Clinical psychologist
9. Registered dietitian or nutrition professional
10. Physician or non-physician practitioner organizations (e.g., group practices) consisting of the individuals identified in 1 through 9 above (e.g., physician clinic).)

In accordance with 42 CFR §424.525(a)(1) and (2), respectively, the contractor (including the NSC) may reject the provider's application if the provider fails to furnish complete information on the enrollment application, including all supporting documentation, within 30 calendar days from the date of the contractor's request for the missing information or documentation.

The 30-day clock identified in 42 CFR §424.525(a) starts on the date that the contractor mails, faxes, or e-mails the pre-screening letter to the provider. If the contractor makes a follow-up request for information, the 30-day clock does not start anew; rather, it keeps running from the date the pre-screening letter was sent.

NOTE: The contractor has the discretion to extend the 30-day time period if it determines that the provider or supplier is actively working with the contractor to resolve any outstanding issues.

The contractor shall also note the following with respect to rejections:

- **PECOS** – The contractor (with the exception of the NSC) shall create an L & T record for paper CMS-855 applications no later than 20 calendar days after receipt of the application in the contractor's mailroom. If the contractor rejects the application and was unable to create an L & T record due to missing data, the contractor shall document the provider file accordingly. If the contractor was able to create the L & T record but rejected the application, the contractor shall flip the status to "rejected" in PECOS.

- **Resubmission after Rejection** – If the provider's application is rejected, the provider must complete and submit a new CMS-855 and all supporting documentation.

- **Appeals** – The provider may not appeal a rejection of its enrollment application.

- **Policy Application –** Unless stated otherwise in this chapter, the policies contained in this section 3.1 apply to all CMS-855 applications identified in sections 2.1 and 2.2 above (e.g., changes of information, reassignments). Thus, suppose an enrolled provider submits a CMS-588. If any information is missing from the form, the contractor shall send a pre-screening letter to the provider.

NOTE: The NSC only collects the CMS-588 for initial DMEPOS supplier enrollment applications (CMS-855S). The NSC does not have to include the CMS-588 in any prescreening letter to a DMEPOS supplier that is not initially applying for a Medicare billing number.

- **Incomplete Responses** – The provider must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. If the provider furnishes some, but not all, of the requested data within the applicable time period, the contractor is not required to contact the provider again to request the rest of the information. It can simply reject the application at the expiration of the aforementioned 30-day period.

- **Notice of Rejection** – If the contractor rejects the application under this section 3.1.1, it shall notify the provider via letter or e-mail that the application is being rejected, the reason(s) for the rejection, and how to reapply. The contractor is free to keep the original application on file after rejection. If the provider requests a copy of its application, the contractor may fax it to the provider.

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter to the provider within the applicable 15-day (Internet-based PECOS applications) or 20-day (paper applications). The provider must furnish all of the missing material or documentation within the applicable timeframe. If the provider fails to do so, the contractor may reject the application.

15.8.3 – Reserved for Future Use

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

15.8.4 – Denials

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

A. Denial Reasons

Per 42 CFR §424.530(a), contractors must deny an enrollment application if any of the situations described below are present, and must provide appeal rights.

When issuing a denial, the contractor shall insert the appropriate regulatory basis (e.g.,

42 CFR §424.530(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter as the basis for denial.

Note that if the applicant is a certified provider or certified supplier and one of the denial reasons listed below is implicated, the contractor need not submit a recommendation for denial to the State/RO. The contractor can simply: (1) deny the application, (2) close out the PECOS record, and (3) send a denial letter to the provider in a format similar to that which is used for carrier denials of non-certified supplier applications (see sections 24 and 25 of this chapter). The contractor shall copy the State and the RO on said letter.

Denial Reason 1 (42 CFR §424.530(a)(1))

The provider or supplier is determined not to be in compliance with the Medicare enrollment requirements described in this section or on the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR part 488.

Note that this denial reason shall be used in the situations described in section 8.4.1, of this chapter.

Denial Reason 2 (42 CFR §424.530(a)(2))

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier who is required to be reported on the CMS-855 is—

- Excluded from Medicare, Medicaid, or any other Federal health care program, as defined in 42 CFR §1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

- Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act.

Denial Reason 3 (42 CFR §424.530(a)(3))

The provider, supplier, or any owner of the provider or supplier was, within the 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include—

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

- Any felonies outlined in section 1128 of the Social Security Act.

While, as discussed in section 27.2(D), of this chapter, the contractor will establish an enrollment bar for providers and suppliers whose billing privileges are revoked, this in no way precludes the contractor from denying re-enrollment to a provider or supplier who was convicted of a felony within the preceding 10-year period or who otherwise does not meet all criteria necessary to enroll in Medicare.

Denial Reason 4 (42 CFR §424.530(a)(4))

The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (The contractor shall contact its DPSE contractor liaison prior to issuing or recommending denial of an application on this ground).

Denial Reason 5 (42 CFR §424.530(a)(5))

The CMS determines, upon onsite review or other reliable evidence, that the provider or supplier is not operational to furnish Medicare covered items or services, or does not meet Medicare enrollment requirements to furnish Medicare covered items or services. This includes, but is not limited to, the following situations:

- The applicant does not have a license(s) or is not authorized by the Federal/State/local government to perform the services for which it intends to render. (In its denial letter, the contractor shall cite the appropriate statute and/or regulations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with).

- The applicant does not have a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider or other person (as set forth in §1833(e) of the Social Security Act).

- The applicant does not meet CMS regulatory requirements for the specialty. (In containing the licensure/certification/authorization requirements for that its denial letter,

the contractor shall cite the appropriate statutory and/or regulatory citations provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with).

- The applicant does not qualify as a provider of services or a supplier of medical and health services. An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in §1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

NOTE: This denial provision should be used in cases where the applicant is not recognized by any Federal statute as a Medicare provider or supplier (e.g., marriage counselors).

- The applicant does not provide a valid SSN/EIN for the applicant, owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

- A home health agency (HHA) does not meet the capitalization requirements outlined in 42 CFR §489.28.

B. Denial Letters

When a decision to deny is made, the carrier shall send a letter to the supplier identifying the reason(s) for denial and furnishing appeal rights. The letter shall follow the format of that shown in section 24 of this chapter.

No reenrollment bar shall be established for denied applications. Reenrollment bars apply only to revocations.

C. Post-Denial Submission of Enrollment Application

A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred:

- If the denial was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.
- If the denial was appealed, the provider or supplier may reapply after it received notification that the determination was upheld.

D. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR §424.530(c), if the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services, the denial may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

E. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 25, of this chapter.

15.8.4.1– Denials for Incomplete Applications

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

This section 8.4.1 only applies to the following individuals and organizations that are submitting an initial application, a change request, or a reassignment:

1. Physicians
2. Physician assistants
3. Nurse practitioners
4. Clinical nurse specialists
5. Certified registered nurse anesthetist
6. Certified nurse-midwife
7. Clinical social worker
8. Clinical psychologist
9. Registered dietitian or nutrition professional
10. Physician and non-physician practitioner organizations (e.g., group practices) consisting of the individuals identified in 1 through 9 above (e.g., physician clinic).

In accordance with 42 CFR §424.530(a)(1), the contractor may deny the provider's application if the provider fails to furnish complete information on the enrollment application, including all supporting documentation, within 30 calendar days from the date of the contractor's request for the missing information or documentation.

The contractor has the discretion to extend the 30-day time period if it determines that the provider or supplier is actively working with the contractor to resolve any outstanding issues.

Note that the concept of "rejection" is no longer applicable to an initial application, reassignment, or change request that is submitted by any of the individuals or organizations identified in 1 through 10 above. Such applications must be denied, not rejected.

The contractor shall also note the following with respect to denials for the submission of incomplete applications:

- **PECOS** – The contractor shall create an L & T record for paper CMS-855 applications no later than 20 calendar days after receipt of the application in the contractor's mailroom. If the contractor denies the application and was unable to create an L & T record due to missing data, the contractor shall document the provider file accordingly. If the contractor was able to create the L & T record but denied the application, the contractor shall flip the status to "denied" in PECOS.

- **Incomplete Responses** – The provider must furnish all missing and clarifying data requested by the contractor within the applicable timeframe. If the provider furnishes some, but not all, of the requested data within the applicable time period, the contractor is not required to contact the provider again to request the rest of the information.

- **Documentation** – The contractor shall document in the file the date on which it completed its pre-screening of the application.

To summarize, if - during the pre-screening process - the contractor finds that data or documentation is missing, it shall send a pre-screening letter the provider within the applicable 15-day (Internet-based PECOS applications) or 20-day (paper applications) pre-screening period. The provider must furnish all of the missing material or documentation within the applicable timeframe. If the provider fails to do so, the contractor must deny the application.

15.8.4.2 – Adverse Legal Actions/Convictions

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Unless stated otherwise, the instructions in this section 8.4.2 apply to the following sections of the CMS-855 application:

- Section 3

- Section 4A of the CMS-855I

- Section 5B (Owning and Managing Organizations)

- Section 6B (Owning and Managing Individuals)

The applicant shall furnish documentation concerning the type and date of the action, what court(s) and law enforcement authorities were involved, and how the adverse action was resolved. It is extremely important that the contractor obtain such documentation, regardless of whether the adverse action occurred in a State different from that in which the provider currently seeks enrollment. In other words, all adverse actions must be fully disclosed, irrespective of where the action took place. In situations where the person or entity in question was excluded but has since been reinstated, the contractor shall verify this through the OIG and ask the applicant to

submit written proof (e.g., reinstatement letter) that such reinstatement has in fact taken place.

If the applicant states in section 3, 4A of the CMS-855I, 5, and/or 6 that the person or entity in question has never had an adverse legal action imposed against him/her/it; but there is evidence to indicate otherwise, the contractor shall make a determination (approve or deny) or contact DPSE for further guidance. (See section 8.4 of this manual for further details on the handling of potentially falsified applications).

If the applicant is excluded or debarred, the contractor shall deny the application in accordance with the instructions in this manual; prior approval from DPSE is not necessary. If any other adverse action is listed, the contractor shall refer the matter to its DPSE contractor liaison for instructions.

If the contractor denies an application or revokes a provider based on an adverse legal action, the contactor shall search PECOS (or, if the provider is not in PECOS, the contractor's internal systems) to determine: (1) whether the provider has any other associations (e.g., is listed in PECOS as an owner of three Medicare-enrolled providers), or (2) if the denial/revocation resulted from an adverse action imposed against an owner, managing employee, director, etc., of the provider, whether the person/entity in question has any other associations (e.g., a managing employee of the provider is identified as an owner of two other Medicare-enrolled HHAs). If such an association is found and, per 42 CFR 424.535, there are grounds for revoking the billing privileges of the other provider, the contractor shall initiate revocation proceedings with respect to the latter.

If the "other provider" is enrolled with a different contractor, the contractor shall notify the latter - via fax or e-mail – of the situation, at which time the latter shall take the revocation action. To illustrate, suppose John Smith attempted to enroll with Contractor X as a physician. Smith is currently listed as an owner of Jones Group Practice, which is enrolled with Contractor Y. Contractor X discovers that Smith was recently convicted of a felony. X therefore denies Smith's application. X must also notify Y of the felony conviction; Y shall then revoke Jones' billing privileges per 42 CFR 424.535(a)(3).

Chain Home Offices, Billing Agencies, and HHA Nursing Registries

If the contractor discovers that an entity listed in sections 7, 8, or 12 of the CMS 855 has had a final adverse action imposed against it, the contractor shall handle the matter in accordance with the instructions in this section 8.4.2.

16.1 – Ordering/Referring Providers Who Are Not Enrolled in Medicare

(Rev. 355, Issued: 09-17-10, Effective: 10-18-10, Implementation: 10-18-10)

The Centers for Medicare & Medicaid Services (CMS) expanded its claim editing of

ordering and referring providers to meet the Social Security Act requirements. Physicians and non-physician practitioners of the types listed below may order items or services for Medicare beneficiaries or may refer Medicare beneficiaries to other Medicare providers or suppliers.

- Doctor of medicine or osteopathy;
- Doctor of dental medicine;
- Doctor of dental surgery;
- Doctor of podiatric medicine;
- Doctor of optometry;
- Doctor of chiropractic medicine;
- Physician assistant;
- Certified clinical nurse specialist;
- Nurse practitioner;
- Clinical psychologist;
- Certified nurse midwife; and
- Clinical social worker.

Over the years, some physicians and non-physician practitioner types listed above have traditionally ordered or referred and are identified in Medicare claims as the ordering or referring provider even though they were not enrolled in the Medicare program. Generally, they were identified in claims by surrogate Unique Physician Identification Numbers (UPINs) (e.g., RES000, OTH000). Medicare claims from providers and suppliers who furnished items or services to Medicare beneficiaries as a result of an order or a referral will not be reimbursed by Medicare for those items or services unless the ordering/referring provider is of the type listed above and has an enrollment record in the Provider Enrollment, Chain and Ownership System (PECOS) at the time of the order or referral. CMS has made the following determinations:

Most physicians and practitioners only enroll in the Medicare program to furnish covered services to Medicare beneficiaries. However, with the implementation of Section 6405 of the Affordable Care Act, CMS has become aware of certain physicians or practitioners who have unique enrollment issues and will need to enroll in the Medicare program for the sole purpose of ordering or referring items or services for Medicare beneficiaries. These physicians and practitioners do not and will not send claims to a Medicare contractor for the services they furnish. Specifically, the process of enrollment to accommodate these physicians and practitioners has been modified. Below are some circumstances of which physicians and practitioners qualify to use the modified application process. If you are:

- Employed by the Department of Veterans Affairs (DVA);

- Employed by the Public Health Service (PHS);
- Employed by the Department of Defense (DOD) Tricare;
- Employed by federally qualified health centers (FQHC), rural health clinics (RHC) or critical access hospitals (CAH);
- Physicians in a fellowship;
- Dentist, including oral surgeons; and
- Any provider can enroll for the sole purpose of ordering or referring, regardless of who their employer is.

The physicians and practitioners described above must do the following:

Complete the paper form CMS-855I, "Medicare Enrollment Application for Physicians and Non-Physician Practitioners," by completing the following sections listed below and mail the completed form to the designated Medicare enrollment contractor:

Section 1 – Basic Information (they would be a new enrollee);

Section 2 – Identifying Information (section 2A, 2B, 2D and if appropriate 2H and 2K);

Section 3 – Final Adverse Actions/Convictions;

Section 13 – Contact Person; and

Section 15 - Certification Statement (must be signed and dated—blue ink recommended.

The physicians and practitioners described above must include a cover letter with their paper form CMS-855I, "Medicare Enrollment Application for Physicians and other Practitioners," stating the provider is only enrolling for the sole purpose of ordering and referring items or services for a Medicare beneficiary to other providers and suppliers and cannot be reimbursed for services performed.

The CMS is not requiring the physicians or practitioners to send the CMS-460, Medicare Participating Physician or Supplier Agreement or the CMS-588, Electronic Funds Transfer (EFT) Authorization Agreement, in with the CMS-855I application. License information received from a physician or practitioner who is employed by the DVA or DOD, may be active in a state other than the DOD or DVA location.

Medicare enrollment contractors shall verify the information sent on the application meets the Medicare requirement for the supplier type and, if the application is approved, will enter the information into the PECOS; hence, the physician or practitioner will be on the ordering/referring file in the Medicare claims system. Contractors will send the appropriate notification letter to inform these physician and

non-physician practitioners that they are enrolled in the Medicare program for the sole purpose of ordering and referring items or services for Medicare beneficiaries to other providers and suppliers.

Since the modified application does not require physicians and practitioners to complete section 4 and we are requiring the cover letter, Medicare enrollment contractors shall reject the application if section 4 is blank and a cover letter is not attached.

Until PECOS is redesigned, the Medicare contractor will use the information provided from the modified application to populate the PECOS required field.

- All effective dates will be the date of receipt;
- Certification Information: Contractor selects N/A;
- PAR Status: Contractor selects "no" for non-par;
- Practice and Special Payment Address: Contractor enters the correspondence address provided for both and select 'other' for the location type and enters 'ordering and referring only';
- Reassignment Information: Contractors selects 'none'; and
- Any additional information that may be needed; the contractor can select the equivalent to 'no', N/A, 'none'.

If, in the future, a physician or practitioner, as described above, with a type listed above, now wishes to be reimbursed by Medicare for services performed, the current information to only order and refer items or services must be deactivated and the new information submitted via the appropriate paper enrollment application(s) or Internet-based PECOS as an update.

Interns and residents cannot enroll in the Medicare program for the sole purpose of ordering items or services for Medicare beneficiaries or referring Medicare beneficiaries to other Medicare providers or suppliers. If an intern or resident orders or refers services to Medicare beneficiaries, the teaching, admitting or attending physician's name and NPI go on the claim as the ordering/referring provider.

NOTE: The action reason code (AR) 51 shall be added by the contractor to the multi-carrier system (MCS) for physician and non-physician practitioners who enroll in Medicare solely to order or refer and so they cannot be reimbursed for any services to Medicare beneficiaries.

15.17 – Establishing an Effective Date of Medicare Billing Privileges
(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

(This section only applies to the following individuals and organizations: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical

psychologists; registered dietitians or nutrition professionals; and physician and non-physician practitioner organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.)

In accordance with 42 CFR §424.520(d), the effective date for the individuals and organizations identified above is the later of the date of filing or the date they first began furnishing services at a new practice location. Note that the date of filing for Internet-based PECOS applications for these individuals and organizations is the date that the contractor received an electronic version of the enrollment application and a signed certification statement.

In accordance with 42 CFR §424.521(a), the individuals and organizations identified above may, however, retrospectively bill for services when:

- The supplier has met all program requirements, including State licensure requirements, and

- The services were provided at the enrolled practice location for up to—

1. 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, or

2. 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

Medicare contractors shall interpret the phase "circumstances precluded enrollment" shown above to mean that that the physician, non-physician practitioner or physician or non-physician practitioner organization meets all program requirements, including State licensure, during the 30 days before an application was submitted and no final adverse action, as identified in 42 CFR § 424.502 precluded enrollment. If a final adverse action precluded enrollment during the 30 day period prior to date of filing, the Medicare contractor shall only establish an effective billing date the day after the date the final adverse action was resolved as long as it is not more than 30 days prior to the date the application was submitted.

15.17.4 - Certified Provider or Supplier Agreement or Approval

(Rev. 372, Issued: 03-25-11, Effective: 10-01-10, Implementation: 04-25-11)

The final FY 2011 IPPS rule was published on August 16, 2010 (75 FR50042) and is effective October 1, 2010. Several provisions in the rule directly affect areas of survey and certification responsibility.

42 CFR 489.13 governs the determination of the effective date of a Medicare provider agreement or supplier approval for health care facilities that are subject to survey and

certification. §489.13 has been revised to make it clearer that the date of a Medicare provider agreement or supplier approval may not be earlier than the latest date on which all applicable federal requirements have been met, and that such requirements include review and verification of an application to enroll in the Medicare program by CMS's legacy fiscal intermediary (FI), legacy carrier, or Medicare Administrative Contractor (MAC).

These clarifications were necessary because a September 28, 2009 decision of the Appellate Division of the Department Appeals Board (DAB) interpreted §489.13 as not including enrollment application processing among Federal requirements that must be met. In that case a State Agency (SA) had conducted a survey of an applicant on July 6, 2007, prior to receiving the November 21, 2007 notice from the legacy FI that was recommending approval of the applicant's enrollment application. The CMS Regional Office (RO) issued a provider approval effective November 21, 2007, consistent with our traditional interpretation of §489.13. The DAB, however, ruled that the effective date must be July 6, 2007. The DAB agreed with the applicant in this case that the requirement for the Medicare contractor to verify and determine whether an application should be approved is not a requirement for the provider to meet [under §489.13], but rather a requirement for Medicare contractor action (DAB Decision No. 2271, page 5).

Although SAs and accreditation organizations (AOs) are aware that, in accordance with Section 2003B of the State Operations Manual (SOM), they should not perform a survey of a new facility until the MAC/legacy FI/legacy carrier has provided notice that the information provided on the enrollment application has been verified and enrollment is being recommended, circumstances do occur when the sequence is reversed. AOs, in particular, often find it challenging to confirm whether the MAC/legacy FI/legacy carrier has completed its review and made a recommendation. This is because AOs are dependent upon the applicant providing copies of the pertinent notices. When the survey occurs prior to the enrollment verification activities, we believe it is essential that the provider agreement or supplier approval date be based on the later date, i.e., the date the contractor determined that the enrollment application verification. There are other Federal requirements not related to a facility's survey, such as the provision of required Office for Civil Rights documentation and additional federal requirements specific to certain provider types, such as IPPS exclusion requirements for certain types of hospitals, capitalization and surety bond requirements for home health agencies, among others.

Accordingly, the revised rule explicitly states in §489.13(b) that:

"Federal requirements include, but are not limited to –

> *(1) Enrollment requirements established in part 424, Subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;*

(2) The requirements identified in §§489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification."

15.18 – Initial Enrollment Determination

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

15.19 – Application Fees and Additional Screening Requirements

(Rev .371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

15.19.1 – Application Fees

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

A. Background

Pursuant to 42 CFR §424.514 - and with the exception of physicians, non-physician practitioners, physician group practices and non-physician group practices – institutional providers that are (1) initially enrolling in Medicare, (2) adding a practice location, or (3) revalidating their enrollment information per 42 CFR §424.515, must submit with their application:

- An application fee in an amount prescribed by CMS, and/or
- A request for a hardship exception to the application fee.

This requirement applies to applications that the contractor receives on or after March 25, 2011.

For purposes of this requirement, the term "institutional provider," as defined in 42 CFR §424.502, means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS- 855B (not including physician and non-physician practitioner organizations), Form CMS-855S or associated Internet-based Provider Enrollment, Chain and Ownership System (PECOS) enrollment application. Note that a physician, non-physician practitioner, physician group, or non-physician practitioner group that is enrolling as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) via the Form CMS-855S application must submit the required application fee with its Form CMS-855S form.

B. Fee

1. Amount

The application fee must be in the amount prescribed by CMS for the calendar year in

which the application is submitted. The fee for March 25, 2011 through December 31, 2011 is $505.00. Fee amounts for future years will be adjusted by the percentage change in the consumer price index (for all urban consumers) for the 12-month period ending on June 30 of the prior year. CMS will give the contractor and the public advance notice of any change in the fee amount for the coming calendar year.

2. Non-Refundable

Per 42 CFR §424.514(d)(2)(v), the application fee is non-refundable, except if it was submitted with one of the following:

a. A hardship exception request that is subsequently approved;

b. An application that was rejected prior to the contractor's initiation of the screening process, or

c. An application that is subsequently denied as a result of the imposition of a temporary moratorium under 42 CFR §424.570.

(For purposes of (B)(2)(b) above, the term "rejected" includes applications that are returned pursuant to section 15.8.1 of this Chapter.)

In addition, the fee should be refunded if:

- It was not required for the transaction in question (e.g., the provider submitted a fee with its application to report a change in phone number).

- It was not part of an application submission.

3. Format

The provider or supplier must submit the application fee electronically through Pay.gov, either via credit card, debit card, or check. Note that CMS will send to the contractor on a regular basis a listing of providers and suppliers (the "Fee Submitter List") that have paid an application fee via Pay.gov.

C. Hardship Exception

1. Background

A provider or supplier requesting a hardship exception from the application fee must include with its enrollment application a letter (and any supporting documentation) that describes the hardship and why the hardship justifies an exception. If a paper Form CMS-855 application is submitted, the hardship exception letter must accompany the application; if the application is submitted via Internet-based PECOS, the hardship exception letter must accompany the certification statement. Hardship exception letters

shall not be considered if they were submitted separately from the application or certification statement, as applicable. If the contractor receives a hardship exception request separately from the application or certification statement, it shall: (1) return it to the provider, and (2) notify the provider via letter, e-mail or telephone that it will not be considered.

2. Criteria for Determination

The application fee for Calendar Year 2011 is $505 and generally should not represent a significant burden for an adequately capitalized provider or supplier. Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including providing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).

Other factors that <u>may</u> suggest that a hardship exception is appropriate include the following:

(a) Considerable bad debt expenses,

(b) Significant amount of charity care/financial assistance furnished to patients,

(c) Presence of substantive partnerships (whereby clinical, financial integration are present) with those who furnish medical care to a disproportionately low-income population;

(d) Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or

(e) Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

Upon receipt of a hardship exception request with the application or certification statement, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its Provider Enrollment Operations Group (PEOG) liaison. PEOG has 60 calendar days from the date of the contractor's receipt of the hardship exception request to determine whether it should be approved; during this period, the contractor shall not commence processing the provider's application. PEOG will communicate its decision to the provider and the contractor via letter, after which the contractor shall carry out the applicable instructions in section 19.1(D) below.

Note that if the provider fails to submit appropriate documentation to support its

request, the contractor is not required to contact the provider to request it. The contractor can simply forward the request "as is" to its PEOG liaison. Ultimately, it is the provider's responsibility to furnish the necessary supporting evidence at the time it submits its hardship exception request.

D. Receipt

Upon receipt of a paper application (or, if the application is submitted via Internet-based PECOS, upon receipt of a certification statement) from a provider or supplier that is otherwise required to submit an application fee, the contractor shall first determine whether the application is an initial enrollment, a revalidation, or involves the addition of a practice location. If the application does not fall within any of these categories, the contractor shall process the application as normal. If it does fall within one of these categories, the contractor shall undertake the following:

a. Determine whether the provider has: (1) paid the application fee via Pay.gov, and/or (2) included a hardship exception request with the application or certification statement. The contractor can verify payment of the application fee by checking:

- Whether the provider has included with its application or certification statement a Pay.gov receipt as proof of payment, and/or

- The Fee Submitter List

b. If the provider:

i. Has neither paid the fee nor submitted the hardship exception request, the contractor shall send a letter to the provider notifying it that it has 30 days from the date of the letter to pay the application fee via Pay.gov, and that failure to do so will result in the rejection of the provider's application (for initial enrollments and new practice locations) or revocation of the provider's Medicare billing privileges (for revalidations). The letter shall also state that because a hardship exception request was not submitted with the original application, CMS will not consider granting a hardship exception in lieu of the fee.

During this 30-day period, the contractor shall review each updated Fee Submitter List to determine whether the fee has been paid via Pay.gov. If the fee is paid within the 30-day period, the contractor may begin processing the application as normal. If the fee is not paid within the 30-day period, the contractor shall reject the application (initial enrollments and new locations) under 42 CFR §424.525(a)(3) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

Note that if, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the

application as normal.

ii. Has paid the fee but has not submitted a hardship exception request, the contractor shall begin processing the application as normal.

iii. Has submitted a hardship exception request but has not paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG liaison. If PEOG:

a. Denies the hardship exception request, it will notify the provider in the decision letter (on which the contractor will be copied) that the application fee must be paid within 30 calendar days from the date of the letter. During this 30-day period, the contractor shall review each updated Fee Submitter List to determine if the fee has been submitted via Pay.gov. If the fee is not paid within 30 calendar days, the contractor shall deny the application (initial enrollments and new locations) pursuant to 42 CFR §424.530(a)(9) or revoke the provider's Medicare billing privileges under 42 CFR §424.535(a)(6) (revalidations).

If, at any time during this 30-day period, the provider submits a Pay.gov receipt as proof of payment, the contractor shall begin processing the application as normal.

b. Approves the hardship exception request, it will notify the provider of such in the decision letter (on which the contractor will be copied). The contractor shall begin processing the application as normal.

iv. Has submitted a hardship exception request and has paid a fee, the contractor shall send the request and all documentation accompanying the request via regular mail, fax, or e-mail to its PEOG liaison. As the fee has been paid, the contractor shall begin processing the application as normal.

In all cases, the contractor shall not begin processing the provider's application until: (1) the fee has been paid, or (2) the hardship exception request has been approved.

E. Appeals of Hardship Determinations

A provider may appeal PEOG's denial of its hardship exception request via the procedures outlined below:

1. If the provider is dissatisfied with PEOG's decision to deny a hardship exception request, it may file a written reconsideration request with PEOG within 60 calendar days from receipt of the notice of initial determination (e.g., PEOG's denial letter). The request must be signed by the individual provider or supplier, a legal representative, or any authorized official within the entity. Failure to file a reconsideration request within this timeframe is deemed a waiver of all rights to further administrative review.

The reconsideration request should be mailed to:

Centers for Medicare & Medicaid Services
Provider Enrollment Operations Group
7111 Security Boulevard
Baltimore, MD 21244

Notwithstanding the filing of a reconsideration request, the contractor shall still carry out the post-hardship exception request instructions in subsections (D)(b)(iii)(a) and (iv) above, as applicable. A reconsideration request, in other words, does not stay the execution of the instructions in section 19.1(D) above.

PEOG has 60 calendar days from the date of the reconsideration request to render a decision. The reconsideration shall be:

(a) Conducted by a PEOG staff person who was independent from the initial decision to deny the hardship exception request.

(b) Based on PEOG's review of the original letter and documentation submitted by the provider.

Upon receipt of the reconsideration, PEOG will send a letter to the provider or supplier to acknowledge receipt of its request. In its acknowledgment letter, PEOG will advise the requesting party that the reconsideration will be conducted and a determination issued within 60 days from the date of the request.

a. If PEOG denies the reconsideration, it will notify the provider of this via letter, with a copy to the contractor. If PEOG approves the reconsideration request, it will notify the provider of this via letter, with a copy to the contractor, after which the contractor shall process the application as normal, or, to the extent applicable:

    i. If the application has already been rejected, request that the provider resubmit the application without the fee, or

    ii. If Medicare billing privileges have already been revoked, reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

Note that Corrective Action Plans (CAPs) may not be submitted in lieu of or in addition to a request for reconsideration of a hardship exception request denial.

2. If the provider is dissatisfied with the reconsideration determination regarding the application fee, it may request a hearing before an Administrative Law Judge (ALJ). Such an appeal must be filed, in writing, within 60 days from receipt of the

reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

If the ALJ reverses PEOG's reconsideration decision and approves the hardship exception request, and the application has already been rejected, the contractor – once PEOG informs it of the ALJ's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

3. If the provider is dissatisfied with the ALJ's decision, it may request Board review by the Departmental Appeals Board (DAB). Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

If the DAB reverses the ALJ's decision and approves the hardship exception request, and the application has already been rejected, the contractor - once PEOG informs it of the DAB's decision - shall notify the provider via letter, e-mail or telephone that it may resubmit the application without the fee. If the provider's Medicare billing privileges have already been revoked, the contractor shall reinstate said billing privileges in accordance with existing instructions and request that the provider resubmit the application without the fee.

To the extent permitted by law, a provider or supplier dissatisfied with a DAB decision may seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

F. Miscellaneous

The contractor shall abide by the following:

1. Paper Checks Submitted Outside of Pay.gov – As stated earlier, all payments must be made via Pay.gov. Should the provider submit an application with a paper

check or any other hard copy form of payment (e.g., money order), the contractor shall not deposit the instrument. It shall instead treat the situation as a non-submission of the fee and follow the instructions in (D)(b)(i) or (iii) above (depending on whether a hardship exception request was submitted). When sending the applicable letter requesting payment within 30 days, the contractor shall explain that all payments must be made via Pay.gov, stamp the submitted paper check "VOID," and include the voided paper check with the letter.

2. Practice Locations – DMEPOS suppliers, federally qualified health centers (FQHCs), and independent diagnostic testing facilities (IDTFs) must individually enroll each site. Consequently, the enrollment of each site requires a separate fee. For **all other providers and suppliers** (except physicians, non-physician practitioners, and physician and non-physician practitioner groups, none of which are required to submit the fee), a fee must accompany any application that adds a practice location. If multiple locations are being added on a single application, however, only one fee is required. The fee for providers and suppliers other than DMEPOS suppliers, FQHCs, and IDTFs is based on the application submission, not the number of locations being added on a single application.

1. Other Application Submissions – A provider or supplier need not pay an application fee if the application is:

   - Reporting a change of ownership via the Form CMS-855B or Form CMS-855S. (For providers and suppliers reporting a change of ownership via the Form CMS-855A, the ownership change does not necessitate an application fee if the change does not require the provider or supplier to enroll as a new provider or supplier.)

   - Reporting a change in tax identification number (whether Part A, Part B, or DMEPOS)

   - Requesting a reactivation of the provider's Medicare billing privileges

15.19.2 – Screening Categories
(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

15.19.2.1 – Background
(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

Consistent with 42 CFR §424.518, newly-enrolling and existing providers and suppliers will, beginning on March 25, 2011, be placed into one of three levels of categorical screening: limited, moderate, or high. The risk levels denote the level of the contractor's screening of the provider when it initially enrolls in Medicare, adds a new practice location, or revalidates its enrollment information.

The contractor shall utilize the screening procedures outlined below for applications it

receives on or after March 25, 2011.

A. Limited

The "limited" level of categorical screening consists of the following provider and supplier types:

- Physicians
- Non-physician practitioners other than physical therapists
- Physician group practices
- Non-physician group practices other than physical therapist group practices
- Ambulatory surgical centers
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities
- Federally qualified health centers
- Histocompatibility laboratories
- Hospitals (including critical access hospitals, Department of Veterans Affairs hospitals, and other federally-owned hospital facilities.
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Organ procurement organizations
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Radiation therapy centers
- Religious non-medical health care institutions
- Rural health clinics
- Skilled nursing facilities

For providers and suppliers in the "limited" category, the contractor shall (unless section 19.2.5 of this Chapter applies) process initial, revalidation, and new location applications in accordance with existing instructions.

B. Moderate

The "moderate" level of categorical screening consists of the following provider and supplier types:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Revalidating home health agencies (HHAs)
- Revalidating DMEPOS suppliers

For providers and suppliers in the "moderate" level of categorical screening, the contractor shall (unless section 19.2.2 of this Chapter applies):

- Process initial, revalidation, and new location applications in accordance with existing instructions; and

- Perform a site visit in accordance with the following:

    - Ambulance suppliers, independent clinical laboratories, physical therapists, and physical therapist groups – The contractor shall conduct a site visit prior to the contractor's final decision regarding the application.

    - CMHCs

        - Initial applications - In addition to the site visit that is currently performed, the contractor shall conduct another site visit after receiving the tie-in notice from the regional office but before the contractor conveys Medicare billing privileges to the CMHC. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.

        - Revalidations – The contractor shall conduct a site visit prior to making a final decision regarding the revalidation application.

        - New location – The contractor shall conduct a site visit of the new location prior to making a recommendation for approval.

    - CORFs, hospices and PXRSs -

        - Initial applications - The contractor shall conduct a site visit after receiving the tie-in notice from the regional office but before the

contractor conveys Medicare billing privileges to the provider. This is to ensure that the provider is still in compliance with CMS's enrollment requirements.

- Revalidations – The contractor shall conduct a site visit prior to making a final decision regarding the revalidation application.

- New location – The contractor shall conduct a site visit of the new location prior to making a recommendation for approval.

- IDTFs

  - Initial applications – The contractor shall conduct site visits of initially enrolling IDTFs in accordance with Pub. 100-08, Chapter 10, section 4.19.6.

  - Revalidations - The contractor shall conduct site visits of revalidating IDTFs (prior to making a final decision regarding the revalidation application) in accordance with Pub. 100-08, Chapter 10, section 4.19.6.

  - Revalidating HHAs – The contractor shall conduct a site visit of the HHA prior to making a final decision regarding the revalidation application.

  - Revalidating DMEPOS suppliers – The contractor shall conduct a site visit of the DMEPOS supplier prior to making a final decision regarding the revalidation application.

C. High

The "high" level of categorical screening consists of the following provider and supplier types:

- Newly enrolling DMEPOS suppliers
- Newly enrolling HHAs

For providers and suppliers in the "high" level of categorical screening, the contractor shall:

- Process initial, revalidation, and new location applications in accordance with existing instructions; and

- Perform a site visit to the extent that this is not already required by CMS. If a site visit is currently required, the contractor shall continue this activity in accordance with existing instructions.

(**NOTE**: Enrolled DMEPOS suppliers that are adding another location will be classified as "high" for screening purposes. In addition, newly-enrolling HHA sub-units fall within the "high" level of categorical screening.)

See section 19.2.3 below for information regarding DMEPOS changes of ownership and TIN changes.

15.19.2.2 - Scope of Site Visit

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

A. DMEPOS Suppliers and IDTFs

As stated above, site visits of DMEPOS suppliers and IDTFs shall continue to be conducted in accordance with existing CMS instructions and guidance.

B. Other Provider and Supplier Types

For all provider and supplier types – other than DMEPOS suppliers and IDTFs – that are subject to a site visit in accordance with this section, the contractor shall perform such visits using the procedures outlined in sections 20 and 20.1 of this Chapter. This includes the following:

- Documenting the date and time of the visit, and including the name of the individual attempting the visit;
- Photographing the provider or supplier's business for inclusion in the provider/supplier's file. All photographs should be date/time stamped;
- Fully documenting observations made at the facility, which could include facts such as: (a) the facility was vacant and free of all furniture; (b) a notice of eviction or similar documentation is posted at the facility, and (c) the space is now occupied by another company;
- Writing a report of the findings regarding each site verification; and
- Including a signed declaration stating the facts and verifying the completion of the site verification. (The sample declaration identified in section 20.1 of this Chapter is recommended.)

In terms of the extent of the visit, the contractor shall determine whether the following criteria are met:

- The facility is open
- Personnel are at the facility

- Customers are at the facility (if applicable to that provider or supplier type)

- The facility appears to be operational

This will require the site visitor(s) to enter the provider or supplier's practice location/site, rather than simply conducting an external review.

If any of the 4 elements listed above are not met, the contractor shall, as applicable - and using the procedures outlined in Pub. 100-08, Chapters 10 and 15 - deny the provider's enrollment application pursuant to §424.530(a)(5)(i) or (ii), or revoke the provider's Medicare billing privileges under §424.535(a)(5)(i) or (ii).

15.19.2.3 – Changes of Information

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

1. Limited

Changes of information (including additions of practice locations) submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

2. Moderate

a. Addition of Practice Location

With the exception of DMEPOS suppliers, if a provider or supplier in the "moderate" level of categorical screening submits a Form CMS-855 request to add a practice location (including an HHA branch), the contractor shall: (1) process the application in accordance with existing instructions, and (2) conduct a site visit in accordance with the instructions in section 19.2.1(B) above.

(As explained earlier, a DMEPOS supplier that is adding a new practice location falls within the "high" screening category.)

b. Change of Ownership

With the exception of DMEPOS suppliers and HHAs, if a provider or supplier undergoes a change of ownership resulting in a new tax identification number (TIN), the contractor shall:

(1) Process the application in accordance with existing instructions, and

(2) Conduct a site visit in accordance with the following:

- For ownership changes that must be approved by the regional office under current CMS instructions, the site visit shall be performed after the

contractor receives the tie-in notice from the regional office but before the contractor activates the new owner's billing privileges.

- For ownership changes that do not require regional office approval under current CMS instructions, the site visit shall be performed prior to the contractor's final decision regarding the application.

A DMEPOS supplier that is:

- Undergoing a change of ownership with a change in TIN falls within the "high" screening category.

- Undergoing a change of ownership with no change in TIN falls within the "moderate" screening category.

- Undergoing a change in TIN with no change in ownership falls within the "moderate screening category.

With respect to HHAs:

- For HHAs undergoing a change in majority ownership, the contractor shall – consistent with section 15.26.1 of this Chapter – determine whether the provisions of 42 CFR §424.550(b)(1) and (2) apply. If the contractor determines that a change in majority ownership has occurred and that none of the exceptions in §424.550(b)(2) apply, the HHA must enroll as a new entity, in which case the newly-enrolling HHA will be placed into the "high" level of categorical screening. If the contractor determines that an exception does apply, the transaction will be subject to the "moderate" level of categorical screening; a site visit will be necessary.

- For HHAs reporting an ownership change that is not a change in majority ownership as that term is defined in §424.502, the contractor shall process the change in accordance with existing instructions. A site visit is not necessary.

- For HHAs seeking to reactivate their Medicare billing privileges, the transaction shall be processed under the "moderate" level of categorical screening. A site visit will be necessary prior to the reactivation of the provider's billing privileges.

c. All Other Changes of Information

All other changes of information for providers and suppliers in the moderate level of categorical screening shall be processed in accordance with existing instructions.

3. High

Unless otherwise specified in sections 19.2.1 through 19.2.5, no changes of information will be subject to the "high" level of categorical screening.

15.19.2.4 – Reactivations

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

A. Limited

Reactivation applications submitted by providers and suppliers in the "limited" level of categorical screening shall be processed in accordance with existing instructions.

B. Moderate

Reactivation applications submitted by providers and suppliers in the "moderate" level of categorical screening – including existing DMEPOS suppliers and HHAs – shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

C. High

Reactivation applications submitted by providers and suppliers in the "high" level of categorical screening shall be processed in accordance with the screening procedures for this category. A site visit will therefore be necessary prior to the contractor's final decision regarding the application.

15.19.2.5 – Movement of Providers and Suppliers into the High Level

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

Under §424.518©(3), CMS may adjust a particular provider or supplier's screening level from "limited" or "moderate" to "high" if any of the following occur:

2. CMS imposes a payment suspension on a provider or supplier at any time within the last 10 years;

3. The provider or supplier:

a. Has been excluded from Medicare by the Office of Inspector General; or

b. Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by:

   i. Enrolling as a new provider or supplier; or
   ii. Obtaining billing privileges for a new practice location

c. Has been terminated or is otherwise precluded from billing Medicaid

d. Has been excluded from any Federal health care program

e. Has been subject to any final adverse action (as defined in §424.502) within the previous 10 years

4. CMS lifts a temporary moratorium for a particular provider or supplier type, and a provider or supplier that was prevented from enrolling based on the moratorium applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

CMS intends to send to the contractor on a bi-monthly basis a list of current and former Medicare providers and suppliers within the contractor's jurisdiction that meet any of the criteria in subsection (1) or (2) above. Upon receipt of an initial, revalidation, or new location application from a provider or supplier that otherwise falls within the limited or moderate screening category (and after the appropriate fee has been paid, etc.), the contractor shall determine whether the provider or supplier is on the bi-monthly "high" screening list. If the provider or supplier is, the contractor shall process the application using the procedures in the "high" screening category. If the provider or supplier is not on said list, the contractor shall process the application in accordance with existing instructions.

With respect to subsection (3) above, if the contractor receives an initial or new location application from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the procedures in the "high" screening category.

15.19.3 – Temporary Moratoria

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

Under §424.570(a), CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. In general, a moratorium will not apply to:

- Reactivations
- Revalidations
- A change in practice location
- A change of ownership (with the exception of situations in which an HHA must enroll as a new HHA in accordance with 42 CFR §424.550(b), in which case the new application is treated as an initial enrollment and is therefore subject to the moratorium)
- Any other change in the provider or supplier's enrollment information

The announcement of a moratorium will be made via the Federal Register, though the contractor will also be separately notified of the moratorium. For initial and new location applications involving the affected provider and supplier type, the moratorium:

- Will not apply to applications for which an approval or a recommendation for approval has been made as of the effective date of the moratorium, even if the contractor has not yet formally granted Medicare billing privileges. Such applications can continue to be processed to completion.

- Will apply to applications that are pending as of the effective date of the moratorium and for which the contractor has not yet made a final approval/denial decision or recommendation for approval. The contractor shall deny such applications, using §424.535(a)(10) as the basis.

- Will apply to applications that the contractor receives on or after the effective date of the moratorium, and for as long as the moratorium is in effect. The contractor shall deny such applications, using §424.535(a)(10) as the basis.

If a particular moratorium is lifted, all applications pending with the contractor as of the effective date of the moratorium's cessation are no longer subject to the moratorium and may be processed. However, consistent with §424.518(a)(3), such applications shall be processed in accordance with the "high" level of categorical screening. In addition, any initial application received from a provider or supplier: (a) that is of a provider or supplier type that was subject to a moratorium and (b) within 6 months after the applicable moratorium was lifted, the contractor shall process the application using the "high" level of categorical screening.

15.19.4 – Tracking

(Rev. 371, Issued: 03-23-11, Effective: 03-25-11, Implementation: 03-25-11)

In April 2011, PEOG will send to each contractor an Excel spreadsheet that the contractor shall complete and submit to its PEOG liaison via e-mail no later than the 15th day of each month. The first report will be due on May 15, 2011. The spreadsheet will contain data elements such as, but not limited to:

- Number of enrolled providers and suppliers in each risk category, broken down by provider/supplier sub-type (e.g., hospital, HHA)

- Amount of fees collected (i.e., fees that were cleared), broken down by provider and supplier type

15.20 – On-site Inspections and Site Verifications

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

All providers and suppliers are subject to unannounced site visits prior to receiving

Medicare billing privileges or subsequent to receiving Medicare billing privileges. Unannounced site visits are designed to confirm that a physician, non-physician practitioner or other provider or supplier is operating at the practice location furnished to Medicare as part of the enrollment process and that the physician, non-physician practitioner or other provider or supplier is in compliance with applicable regulation provisions for their provider or supplier types.

Carriers, fiscal intermediaries and A/B MACs shall not conduct site verifications to determine if a provider or supplier, including physician and non-physician practitioners, is operational unless CMS has already issued formal guidance or unless CMS issues instructions directing the Medicare contractor to conduct a pre-enrollment site verification or post-enrollment site verification.

The IDTFs shall be excluded from these instructions.

15.20.1 - Site Verifications to Determine Operational Status

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

When conducting a site verification to determine whether a practice location is operational, the Medicare contractor shall make every effort to limit its site verification to an external review of the practice location to determine if it is operational. If the Medicare contractor cannot determine if the practice location is operational based on an external review of the practice location, the Medicare contractor shall conduct an unobtrusive site verification by limiting its encounter with provider or supplier personnel or medical patients.

When conducting site verifications to determine whether a practice location is operational, the Medicare contractor shall:

- Document the date and time of the attempted visit to include the name of the individual attempting the visit;

- As appropriate, photograph the provider or supplier's business for inclusion in the supplier's file on an as needed basis. All photographs should be date/time stamped;

- Fully document observations made at the facility which could include facts such as; the facility was vacant and free of all furniture, a notice of eviction or similar documentation is posted at the facility, the space is now occupied by another company;

- Write a report of their findings regarding each site verification; and

- Include a signed declaration stating the facts and verifying the completion of the site verification. (A sample declaration is below and may be revised as necessary)

Declaration of <u>(Name of Inspector/Investigator)</u>

In the Case of _____
Provider/Supplier No._____

I, **(Name of Inspector/Investigator)**, declare as follows:

1. I have personal knowledge of each of the following matters in this Declaration except to those facts alleged on information and belief, and as to those matters, I believe them to be true. I am competent to testify to the following:

2. I am an Investigator for [Insert Contractor Name]. [Insert Contractor Name] is a CMS-contracted [Intermediary/Carrier/A/B Medicare Administrative Contractor (MAC)].

3. I have been trained as an Investigator and Site Inspector by [Insert Contractor Name], and I am knowledgeable of Medicare's compliance statutes, regulations and standards for suppliers enrolled in the Medicare program. I have worked in this capacity for [Insert years] years. During this period, I have conducted over [Insert Number] site inspections of the offices and facilities of providers/suppliers; and since January [Year in which case occurs], I have conducted over [Insert Number] site inspections related to the compliance of suppliers with Medicare's requirements.

4. I prepared the attached document entitled "[Title of Document]," which is the report of my attempts to inspect Petitioner's facility. This report is a true and accurate account of the events that occurred and transpired on the dates described therein. I am capable and willing to testify as a witness at a hearing about the content of this report.

5. The foregoing information is based on my personal knowledge or is information provided to me in my official capacity. I declare under penalty of perjury that this information is true and correct to the best of my knowledge and belief.

Executed this _**(Date)**__ day of _**(Month) (Year)**_ in _**(City)**_, _**(State)**_.

_____
SIGNATURE OF DECLARANT

Site verifications should be done Monday through Friday (excluding holidays) during their posted business hours. If there are no hours posted, the site verification should occur between 9 a.m. and 5 p.m. If during the first attempt, there are obvious signs that facility is no longer operational no second attempt is required. If, on the first attempt the facility is closed but there are no obvious indications the facility is non-operational, a second attempt on a different day during posted hours of operation should be made.

If a physician, non-physician practitioner, or other provider or supplier is determined not to be operational, the Medicare contractor shall revoke the Medicare billing privileges of the provider or supplier, unless the provider or supplier has submitted a change which notified the Medicare contractor of a change in practice location. Within 7 calendar days of CMS or the Medicare contractor determining that the provider or

supplier is not operational, the Medicare contractor shall update PECOS or the applicable claims processing system (if the provider does not have an enrollment record in PECOS) to revoke billing Medicare billing privileges and issue a revocation notice to the provider or supplier. The Medicare contractor shall use either 42 CFR §424.535(a)(5)(i) or 42 CFR §424.535(a)(5)(ii) as the legal basis for revocation. Consistent with 42 CFR §424.535(g), the date of revocation is the date that CMS or the Medicare contractor determines that the provider or supplier is no longer operational. The Medicare contractor shall establish a 2-year enrollment bar for suppliers that are not operational. The Medicare contractor shall afford the provider or supplier with the applicable appeal rights in the revocation notification letter.

15.20.2 - Site Verifications to Determine if a Provider or Supplier Meets or Continues to Meet the Regulatory Requirements for Their Provider or Supplier Type

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

When conducting a site verification to determine whether a provider or supplier continues to meet the regulatory provisions for the provider or supplier type, the Medicare contractor shall conduct its site verification in a manner which limits the disruption for the provider or supplier.

When conducting site verifications to determine whether a provider or supplier continues to meet the regulatory provisions for the provider or supplier type, the Medicare contractor shall:

- Document the date and time of the attempted visit to include the name of the individual attempting the visit;

- As appropriate, photograph the provider or supplier's business for inclusion in the supplier's file on an as needed basis. All photographs should be date/time stamped;

- Fully document observations made at the facility which could include facts such as; the facility was vacant and free of all furniture, a notice of eviction or similar documentation is posted at the facility, the space is now occupied by another company; and

- Write a report of their findings regarding each onsite inspection; and

- A signed declaration stating the facts and verifying the completion of the site verification. (Refer to section 22.1 for a sample declaration.)

Site verifications should be done Monday through Friday (excluding holidays) during their posted business hours. If there are no hours posted, the site verification should occur between 9 a.m. and 5 p.m. If during the first attempt, there are obvious signs that facility is no longer operational no second attempt is required. If, on the first attempt the facility is closed but there are no obvious indications the facility is non-operational,

a second attempt on a different day during posted hours of operation should be made.

If a Medicare contractor determines that the provider or supplier does not comply with the regulatory provisions for their provider or supplier type, the Medicare contractor shall revoke the provider or supplier's Medicare billing privileges. Within 7 calendar days of CMS or the Medicare contractor determining that the provider or supplier does not comply with the regulatory provisions for their provider or supplier type, the Medicare contractor shall update PECOS or the applicable claims processing system (if the provider does not have an enrollment record in PECOS) to revoke billing Medicare billing privileges and issue a revocation notice to the provider or supplier. The Medicare contractor shall use 42 CFR §424.535(a)(1) as the legal basis for revocation. Consistent with 42 CFR §424.535(g), the date of revocation is the date that CMS or the Medicare contractor determines that the provider or supplier is no longer in compliance with regulatory provisions for their provider or supplier type. The Medicare contractor shall establish a 2-year enrollment bar for the providers and suppliers that are not in compliance with provisions for their enrolled provider or supplier type. The Medicare contractor shall afford the provider or supplier with the applicable appeal rights in the revocation notification letter.

15.20.3 - National Supplier Clearinghouse (NSC)

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

The (NSC) shall continue to conduct onsite inspections consistent with their Statement of Work and any instructions issued by the NSC project officer.

15.21.7.1 – Claims Against Surety Bonds

(Rev.)

15.24 – Model Correspondence Letters

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model provider enrollment letter format or some similar variation and standard language paragraphs.

NOTE: These are model letters and should be adjusted on a case by case basis, if needed. The fill-in-the-blank information (specific to each contractor determination) is in brackets. The contractor must ensure that the information identified in each section of the model letters below are included and addressed, as needed.

15.24.1 – Model Acknowledgement Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Supplier name]:

Your Medicare enrollment application [insert application type] was received on [date] and is/are currently being reviewed. You will receive a letter within 30 calendar days if we need any additional information.
[Insert this language if a reference number is provided: Your application reference number is: (insert reference number)]

Please retain this letter [insert this language if a reference number is provided: (insert reference number)] in the event that you must submit additional information in support of your application. If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.2 – Model Development Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We have received your Medicare enrollment application(s). In order to complete processing your application(s), we request the following revisions and/or supporting documentation. Consistent with regulations found at 42 CFR 424.525, we may reject your application(s) if you do not furnish complete information within 30 calendar days

of the postmark date of this letter.

Requested Revisions:

(The following are examples)

- [Insert section number and subsection letter (if applicable)]

    - [Insert a brief description of the revision(s) needed. Try to limit the description(s) to two sentences or less. (See examples below.)]

- Section 1A
    - National Provider Identifier

- Section 6 and 16
    - Complete these sections for each Delegated Official

- Section 15
    - Print, sign and date this section to approve the changes requested

- Section 17
    - Completed Form CMS-460, Medicare Participating Physician or Supplier Agreement

- If a Change of Ownership (CHOW), provide your Medicare Year-End Cost Report date (Month & Day)

To facilitate the processing of your application(s), you should submit the requested revisions and/or supporting documentation within 30 days to the address listed below:

[Insert contact address]

Finally, please attach a copy of this letter with your revised application(s). If you have any questions, please contact our office at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]
[Enclosure]

15.24.3 – Model Rejection Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are rejecting your Medicare enrollment application(s) and returning your application(s) for the following reason(s):

FACTS: [Insert ALL rejection reason(s) and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

In compliance with Federal regulations found at 42 CFR 424.525, providers and suppliers are required to submit complete application(s) and all supporting documentation within 30 calendar days from the postmark date of the contractor request for missing/incomplete information. If you would like to resubmit an application, you must complete a new Medicare enrollment application(s). Please make sure to address the issues stated above as well as sign and date the new certification statement page on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the

hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.4 – Model Returned Application Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

[Insert application reference number]

Dear [Insert Provider/Suppler name]:

We received your Medicare enrollment application(s) on [insert date]. We are closing this request and returning your application(s) for the following reason(s):

FACTS: [Insert ALL return reason(s) and cite the applicable regulatory authority, if applicable]

In order to resubmit your application(s) you must complete the [insert application type] application(s) with an original signature and date before we can begin processing your application(s). Please make sure to address the issues stated above on your resubmitted application(s).

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS

suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

You should return the complete application(s) to the address listed below:

[Insert contact address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.5 – Model Revalidation Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler name]:

Consistent with Medicare regulations found at 42 CFR 424.515, [insert contractor name], a Medicare contractor, requires that you complete and submit a Medicare enrollment application(s) and submit all applicable supporting documentation within 60 calendar days of the postmark date of this letter.

Providers and suppliers (except DMEPOS suppliers) can enroll in the Medicare program using either the:

1. Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

2. Paper application process. To apply by paper, download and complete the Medicare enrollment application(s) from the Centers for Medicare & Medicaid Services (CMS) Web site at http://www.cms.hhs.gov/MedicareProviderSupEnroll. DMEPOS

suppliers that would like to apply should download and complete the paper application(s) and sent to the National Supplier Clearinghouse (NSC).

While the submission of your Medicare enrollment application(s) will start your 5-year revalidation cycle, you are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Failure to submit complete enrollment application(s) and all supporting documentation within 60 calendar days of the postmark date of this letter may result in your Medicare billing privileges being revoked.
Please return the completed application(s) to:

[Insert application return address]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours] or visit our Web site at [insert Web site] for additional information regarding the enrollment process or the [insert application type].

Sincerely,

[Your Name]
[Title]
[Enclosure]

15.24.6 – Model Approval Recommended Letter for Part A Providers & Certified Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

[Name of contractor] has processed your Medicare enrollment application [insert application type] to enroll in the Medicare Program and have made our preliminary assessment and forwarded it to the Centers for Medicare & Medicaid Services (CMS) regional office for review. The next step of the enrollment process involves a site visit or survey conducted by a State Survey Agency or a CMS approved deemed accrediting organization to ensure compliance with the Conditions of Participation for your provider or supplier type. Once the regional office confirms that your organization meets the Conditions of Participation for your provider or supplier type, we will finalize our review of your enrollment application.

If you have any questions concerning this letter, please contact the State or CMS regional office at [insert phone number(s)].

Sincerely,

[Your Name]
[Title]
Enclosure
cc:

15.24.7 – Model Approval Letter for Initial Enrollment

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We are pleased to inform you that your Medicare enrollment application is approved. Listed below is the information reflected in your Medicare enrollment record, including

your National Provider Identifier (NPI) and Provider Transaction Access Number (PTAN).

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, please contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claim submissions. Your PTAN is also activated for use and will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the interactive voice response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure. Because the PTAN is not considered a Medicare legacy identifier, do not report this identifier to the National Plan and Provider Enumeration System (NPPES) as an "other" provider identification number.

Medicare Enrollment Information

Provider \ Supplier name:	[Insert name]
Practice location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with this initial determination or have any questions regarding the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

You are required by regulations found at 42 CFR 424.516 to submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a

Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Additional information about the Medicare program, including billing, fee schedules, and Medicare polices and regulations can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at http://www.cms.hhs.gov/home/medicare.asp.

Sincerely,

[Your Name]
[Title]

15.24.8 – Model Approval Letter for Change of Information

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have approved your information change request. Listed below is the [insert "new" or "updated"] information reflected in your Medicare enrollment record.

Medicare Enrollment Information

Provider \ Supplier name: [Insert name]

[Insert revised item on the application]:	[Insert updated or changed item on the application]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert active or inactive PTAN]
Specialty:	[Insert provider/supplier specialty]
You are a:	[Insert participating or non-participating]
Effective date [Insert "of termination" if the applicant is voluntarily terminating Medicare participation]	[Insert effective date or effective date of termination]
If a Change of Ownership (CHOW, insert Medicare Year-End Cost Report date:	[Insert Month and Day]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

ADDITIONAL INFORMATION

If you are an existing Medicare provider and currently do not submit claims electronically, or are new to the Medicare program and plan on filing claims electronically, contact our EDI department at [insert phone number]. To start billing the Medicare program, you must use your NPI on all Medicare claims submissions. Your PTAN will be the required authentication element for all inquiries to customer service representatives (CSRs), written inquiry units and the Interactive Voice Response (IVR) system for inquiries concerning claims status, beneficiary eligibility and to check status or other supplier related transactions, therefore keep your PTAN secure.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the

Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

15.24.9 – Model Revalidation Approval Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

NOTE: Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision. Accordingly, a physician, non-physician practitioner and a physician or non-physician practitioner group may not formally appeal the established effective date of billing. Of course, if a physician or non-physician practitioner and a physician or non-physician practitioner group notify a Medicare contractor that an error may have occurred, the contractor should review this matter.
CMS alpha representation
Contractor

[Month Day & Year]
[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Dear [Insert Provider/Suppler name]:

We have processed your Medicare enrollment application(s) to revalidate your Medicare enrollment information.

Listed below is the information reflected in your Medicare enrollment record.

Medicare Enrollment Information:

Provider Name:	[Insert name]
Practice Location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Provider Transaction Access Number (PTAN):	[Insert PTAN]
You are a:	[Insert participating or non-participating]
Effective Date:	[Insert month day, year]

(Repeat for multiple, if necessary, for each additional location and NPI/PTAN combination)

Please verify the accuracy of your enrollment information. If you disagree with the information above, call [insert applicable Medicare contractor name] at [insert Medicare contractor phone number] between the hours of [insert hours of operation]. Per regulations 42 CFR 405.874, a provider or supplier may only appeal a denial or revocation decision.

To maintain an active enrollment status in the Medicare program, regulations found at 42 CFR 424.516 require that you submit updates and changes to your enrollment information in accordance with specified timeframes. Reportable changes include, but are not limited to changes in: (1) legal business name (LBN)/tax identification number (TIN), (2) practice location, (3) ownership, (4) authorized/delegated officials, (5) changes in payment information such as changes in electronic funds transfer information and (6) final adverse legal actions, including felony convictions, license suspensions or revocations of a health care license, an exclusion or debarment from participation in Federal or State health care program, or a Medicare revocation by a different Medicare contractor.

Providers and suppliers may enroll or make changes to their existing enrollment in the Medicare program using the Internet-based Provider Enrollment, Chain and Organization System (PECOS). To apply via the Internet-based PECOS or to download the CMS-855 enrollment applications, go to http://www.cms.hhs.gov/MedicareProviderSupEnroll.

Sincerely,

[Your Name]
[Title]

15.24.10 – Model Denial Letter for Certified Providers & Suppliers: Denial Based on a Condition of Participation

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is denied based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or a corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice]

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such

exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.11 – Model Denial Letter for Certified Providers & Suppliers: Denial Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program. If the certified provider or certified supplier is denied (i.e., ambulatory surgery center (ASC) and portable x-ray) based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Denial

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., hospital, skilled nursing facility, hospice].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.12 – Model Denial Letter for Suppliers, Non-IDTF, Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.530 to view circumstances that warrant a fee-for-service contractor to deny a provider or supplier's enrollment in the Medicare program.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: [insert decision]

Dear [Insert Provider/Suppler name]:

We have received your request to enroll in the Medicare program. However, your application request to receive Medicare payment is denied. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirement to qualify as a [insert provider or supplier type e.g., doctor of medicine, physicians assistant, nurse practitioner].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contact address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You

must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[Insert contact address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.13 – Model Denial Letter for IDTFs

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 410.33 for the IDTF performance standards and requirements.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

Re: [Subject]

Dear [Insert Provider/Suppler Name]:

We have received your request to enroll in the Medicare program. After reviewing the submitted Medicare enrollment application(s), it was determined that you do not meet the conditions of enrollment or meet the requirements to qualify as an Independent Diagnostic Testing Facility (IDTF). Accordingly, your application(s) to enroll in the Medicare program is denied.

In order to obtain Medicare billing privileges, an IDTF must meet all of the performance standards found at 42 CFR 410.33. [Insert Provider Name] failed to meet the following standards:

STANDARDS: [Insert ALL performance standards not met].

FACTS: [Insert ALL the reason(s) for denial and cite the applicable regulatory authority that corresponds to the performance standards not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Contractor Address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Contractor Address]

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.14 – Model Revocation Letter for Certified Providers &

Suppliers: Revocation Based on a Condition of Participation
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on a condition of participation, then the applicant or enrolled entity must submit a reconsideration or corrective action plan with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.
FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the

findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

Enclosure [Attach a copy of the development letter if applicable]

15.24.15 – Model Revocation Letter for Certified Providers & Suppliers: Revocation Based on an Enrollment Reason(s)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges. If the certified provider or certified supplier (i.e., ambulatory surgery center (ASC) and portable x-ray) is revoked based on an enrollment reason(s), then the applicant or enrolled entity must file a reconsideration with CMS.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Pursuant to 42 CFR 424.545(a), this action will also terminate your corresponding provider agreement.

FACTS: [Insert ALL the reason(s) for revocation and cite the applicable regulatory authority]

(Repeat for multiple, if necessary)

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

If you have any questions regarding this letter, please call [phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.16 – Model Revocation Letter for Suppliers Furnishing Part B Services

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

See 42 CFR 424.535 to view the circumstances that warrant a fee-for-service contractor to revoke a provider or supplier's Medicare billing privileges.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Suppler name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert effective date of revocation]. Note: The revocation date in this letter must comport to the provisions found in 42 CFR 424.535(g).

FACTS: [Insert ALL reason(s) for revocation and cite the applicable regulatory authority]

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

Pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time]. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your provider or supplier type.

[The following statement should only be used if a contractor determines that a Final Adverse Action occurred: Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.17 – Model Revocation Letter for OIG Sanctioned Providers/Suppliers

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & ZIP Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Provider/Supplier name]:

This letter is to inform you that your Medicare Provider Transaction Access Number (PTAN) [insert PTAN number] that is associated to the National Provider Identifier (NPI) [insert NPI number] has been revoked effective [insert date of OIG debarment or exclusion].

According to federal regulations 42 CFR 424.535(a)(2), the provider or any owner, managing employee, authorized or delegated official, medical director, supervising physician or other health care personnel of the provider or supplier who has been debarred, suspended or excluded from the Medicare, Medicaid or any other Federal health care or other government program, cannot maintain enrollment in the Medicare program. According to information obtained from the U.S. Department of Health & Human Services (Office of Inspector General), [insert provider/supplier name] has been excluded from participating in the Medicare program.

FACTS: The Department of Health and Human Services, Office of Inspector General notified us that you are excluded from the Medicare, Medicaid, or any other Federal health care program as defined in 42 CFR 1001.2; in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act. You are excluded as of [insert effective date of exclusion] for [Cite the regulatory basis for exclusion. For example: 1128(b)(14)-Default on health education loan and scholarship obligations].

You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action. However, if you believe that this revocation is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must

request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. The reconsideration request must be signed and dated by the individual provider or authorized or delegated official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action]. The request for reconsideration should be sent to:

[For Part B Supplier, insert contractor address]
[For Certified Providers/Suppliers, insert CMS address]

Finally, in accordance with 42 CFR 424.565, [insert name of contractor] is assessing an overpayment in the amount of [insert dollar amount] because the physician or non-physician practitioner continued to furnish services to Medicare beneficiaries after a final adverse action precluded enrollment in the Medicare program.] [Note: As stated in 42 CFR 424.565, Medicare contractors should assess an overpayment back to January 1, 2009, not the date of the final adverse action if the adverse action occurred prior to January 1, 2009.]

If you have any questions regarding this letter, please call [insert phone number] between the hours of [insert office hours]

Sincerely,

[Your name]
[Title]

15.24.18 – Model Revocation Letter for National Supplier Clearinghouse (NSC)

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Supplier Name]
[Address]
[City, State & Zip Code]

RE: Notice of Revocation of Medicare Billing Privileges

Dear [Insert Supplier Name]:

This is to inform you that your Medicare billing privileges are being revoked effective [insert date 30 days from the date of the letter], 30 days from the postmark date of this letter.

The durable medical equipment Medicare administrative contractors (DME MACs) use these numbers to identify suppliers. This revocation has the concurrence of the Centers for Medicare & Medicaid Services (CMS). In addition, pursuant to 42 CFR 424.535(c), [insert contractor name] is establishing a re-enrollment bar for a period of [insert amount of time] year(s) from the effective date of the revocation. This enrollment bar only applies to your participation in the Medicare program. In order to re-enroll, you must meet all requirements for your supplier type.

[This next paragraph will be included if a response to the development request was received in the field below, remember the date needs to be written out.]

The Supplier Audit and Compliance Unit (SACU) reviewed and evaluated the documents you submitted in response to the developmental letter dated [insert date]. This developmental letter afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). However, after review of the information, it has been determined that you have not demonstrated compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

[The next paragraph will be included if a response to the development request was not received.]

The Supplier Audit and Compliance Unit (SACU) has not received a response to the developmental letter sent to you on [insert date]. This request afforded you the opportunity to demonstrate your full compliance with the durable medical equipment, prosthetics & orthotics standards (DMEPOS) supplier standards and/or to correct the deficient compliance requirement(s). Therefore, we have determined that you are not in compliance with the supplier standards noted below:

STANDARDS: [Insert ALL performance standard(s) not met and cite the applicable regulatory authority that corresponds to the performance standard(s) not met e.g., 42 CFR 410.33(c), 42 CFR 410.33(g)(4)(i) and 42 CFR 410.33(g)(5)(ii)].

For Example: Supplier standard number one states that a supplier “Operates its

business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements." Explanation of specific deficiency goes here [regulatory cite to applicable standard(s) for revocation]

Section 1834 (j) of the Social Security Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items furnished by a supplier unless the supplier has a valid Medicare billing number. Therefore, any expenses for items you supply to a Medicare beneficiary on or after the effective date of the revocation of your billing numbers are your responsibility and not the beneficiary's, unless you have proof that you have notified the beneficiary in accordance with section 1834 (a) (18) (ii) of the Social Security Act, and the beneficiary has agreed to take financial responsibility if the items you supply are not covered by Medicare. You will be required to refund on a timely basis to the beneficiary (and will be liable to the beneficiary for) any amounts collected from the beneficiary for such items. If you fail to refund the beneficiary as required under 1834 (j) (4) and 1879 (h) of the Social Security Act, you may be liable for Civil Monetary penalties.

If you believe that you are able to correct the deficiencies and establish your eligibility to participate in the Medicare program, you may submit a corrective action plan (CAP) within 30 calendar days after the postmark date of this letter. The CAP should provide evidence that you are in compliance with Medicare requirements. The National Supplier Clearinghouse (NSC), with Centers for Medicare & Medicaid Services (CMS) approval, may reinstate your supplier number after it reviews your CAP and any additional evidence you submit and determines you are now in compliance with all supplier standards [see 42 C.F.R. 424.57(c)]. CAP requests should be sent to:

[Insert contract address]

If you believe that this determination is not correct, you may request a reconsideration before a contractor hearing officer. The reconsideration is an independent review and will be conducted by a person who was not involved in the initial determination. You must request the reconsideration in writing to this office within 60 calendar days of the postmark date of this letter. The request for reconsideration must state the issues, or the findings of fact with which you disagree and the reasons for disagreement. You may submit additional information with the reconsideration request that you believe may have a bearing on the decision. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review. The request must be made in writing and signed by an authorized official, owner or partner of the business. [The following statement should only be used if the denial involves exclusions or sanction: You may not appeal through this process the merits of any exclusion by another Federal agency. Any further permissible administrative appeal involving the merits of such exclusion must be filed with the Federal agency that took the action.] The request for reconsideration should be sent to:

[Insert contact address]

If you choose not to request a reconsideration of this decision, or you do not receive a favorable decision through the administrative review process, you must wait [insert number of year(s)] before resubmitting your CMS-855S application, per the re-enrollment bar cited above. Applications received in the NSC prior to this timeframe will be returned.

If you have any questions regarding this determination, please contact [insert contact name] at [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.19 – Model Reconsideration Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]

[Reference number]

Dear [Insert Provider/Suppler name]:

This decision letter is in response to your reconsideration request received by [insert contractor name]. The reconsideration request is based on the above referenced provider or suppliers [revocation or denial]. The initial determination letter was dated [insert date of initial determination letter] and thus, this appeal is timely submitted. This letter contains the decision.

The decision is based on Social Security Act, Medicare regulations and/or CMS manual instructions. This decision is based on the evidence in the file, and any information that you may have sent with or since the time of your hearing request.

FACTS: [Insert Regulation]

RATIONALE: [Insert denial/revocation rationale based on the regulation]

(Repeat for multiple, if necessary)

SUMMARY OF SUBMITTED DOCUMENTATION: [Insert all documentation/supporting information submitted]

EVALUATION OF SUBMITTED DOCUMENTATION: [Insert evaluation of documentation/supporting information submitted]

DECISION: All of the documentation in the file for this case has been reviewed and the decision has been made in accordance with Medicare guidelines as outlined in [insert regulation]. Specifically, [name of provider/supplier] [has or has not] provided evidence to show you have fully complied with the standards for which you were [revoked or denied]. Therefore, we [grant or cannot grant] you access to the Medicare Trust Fund (by way or issuance) of a Medicare number.

This decision is [a FAVORABLE DECISION (or) an UNFAVORABLE DECISION]. Please see below for additional appeal rights.

FURTHER APPEAL RIGHTS: ADMINISTRATIVE LAW JUDGE (ALJ)

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request a final ALJ review, you must act quickly and you must meet the requirements for requesting a final ALJ review. You must file your appeal within 60 calendar days after the date of receipt of this decision by writing to the following address:

Department of Health and Human Services
Departmental Appeals Board
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Building, Room G-644
Washington, D.C. 20201
Attn: CMS Enrollment Appeal

Appeal rights can be found at 42 CFR 498. The regulation explains the appeal rights following the determination by the Centers for Medicare & Medicaid Services as to whether such entities [meet and/or continue to meet] the requirements for enrollment in the Medicare program.

If you have any questions regarding this decision, please call [insert phone number] between the hours of [insert office hours].

Sincerely,

[Your Name]
[Title]

15.24.20 – Model Identity Theft Prevention Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall use the following model letter for changes of information and reassignment enrollment applications received, paper and web-submitted, where suspicious provider/supplier enrollment activity may be suspected, except in circumstances where the application can be returned based on the manual instructions. This model letter shall be sent to the address previously established and on file.

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier]
[Address]
[City, State & ZIP Code]

Dear [Insert Provider/Suppler]:

As a security precaution, we are writing to confirm that you submitted a Medicare enrollment application(s) to enroll or change an existing enrollment at the following address:

[Insert Provider/Supplier Address]

If this application was submitted without your authorization, please call the Medicare contractor that processes your claims. The Medicare Fee-For-Service contact information can be found at www.cms.hhs.gov/MedicareProviderSupEnroll.

We will process your application(s) according to The Centers for Medicare & Medicaid (CMS) timeliness standards and will contact you if there is a need for additional information. We will notify you once processing is complete.

Please contact our office with any questions at [insert phone number] between the hours of [insert office hours] and refer to your application(s) reference number [insert reference number].

Sincerely,

[Your Name]

[Title]

24.21 – Model Approval Letter for Providers Who Order and Refer Only

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

CMS alpha representation
Contractor

[Month Day & Year]

[Provider/Supplier Name]
[Address]
[City, State & Zip Code]
Dear [Insert Provider/Suppler name]:

We are pleased to inform you that you are in the Medicare program for the sole purpose of ordering and referring items or services for Medicare beneficiaries to other providers and suppliers. Listed below is the information reflected in your Medicare record.

Medicare Enrollment Information

Provider\supplier name:	[Insert name]
Practice location:	[Insert address]
National Provider Identifier (NPI):	[Insert NPI]
Specialty:	[Insert provider/supplier specialty]

Please verify the accuracy of your information. If you disagree with any portion of this initial determination or have any questions, please call your Medicare Fee-For-Service contractor at [insert phone number] between the hours of [insert office hours].

Additional information about the Medicare program, including billing, fee schedules, and Medicare polices and regulations can be found at our Web site at [insert Web site address] or the Centers for Medicare & Medicaid Services' (CMS) Web site at www.cms.hhs.gov/home/medicare.asp.

Sincerely,

[Your Name]
[Title]

15.25 – Appeals Process

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

A provider or supplier whose Medicare enrollment is denied or whose Medicare billing privilege is revoked can request an appeal of that determination. In addition, some providers and suppliers may submit an appeal for any type of application submitted (i.e., initial application, change request or reassignment) that resulted in a denial.

This appeal process applies to all providers and suppliers, not just those defined in 42 CFR §498, and ensures that all applicants receive a fair and full opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request an appeal of a reconsideration decision to an administrative law judge (ALJ) of the Department of Health and Human Services (DHHS). Providers and suppliers then can seek review by the Departmental Appeals Board (DAB) and then may request judicial review.

Denial/Revocation of Medicare Billing Privileges

A. Carriers (including NSC and A/B MACs)

If a Medicare contractor reviews an initial enrollment application for a provider or supplier and finds a basis for denying the application pursuant to 42 CFR §424.530, such as; the provider or supplier does not meet one or more of the Federal or State requirements, the Medicare contractor shall deny the application and notify the provider or supplier by letter. The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;
- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;
- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;
- Procedures for submitting a corrective action plan (CAP); and
- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or supplier's billing privileges, such as; the provider or supplier no longer

meets one of the requirements for billing privileges, the contractor shall revoke billing privileges and notify the provider or supplier by letter. The revocation letter shall contain:

- A legal (i.e., regulatory) basis for each reason for revocation;

- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;

- The effective date of the revocation (30 days from the date the notice is mailed for providers or suppliers, or 15 days from the date the notice is mailed for DMEPOS suppliers. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation;

- Procedures for submitting a CAP; and

- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Actions Plan (CAP)

A CAP is the process that gives the provider or supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The Medicare contractor, including the NSC, shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days from the date of the notice. All part B certified supplier CAP requests should be forwarded to CMS for processing at:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment

7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

The CAPs shall be submitted in the form of a letter and shall contain, at a minimum, verifiable evidence of provider or supplier compliance with enrollment requirements. The letter shall be signed and dated by the individual provider, the authorized or delegated official or a legal representative. Contractors may also create a standard CAP form to be sent out with their denial letters to easily identify it as a CAP when it is returned.

Contractors may accept a CAP by fax. If all the missing information originally requested is not received contractors should make one contact to the provider or supplier, preferably via e-mail or fax, to obtain the additional information before making a final determination. Contractor may use the model development letter, found in section 14 of this chapter, to request the information.

If a CAP for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. Contractors shall notify the applicant via letter that the enrollment has been approved. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application. For an approved CAP, contractors shall use the receipt date of the CAP request as the receipt date they enter in PECOS.

For DMEPOS suppliers the effective date is the date it is awarded by the NSC. CMS' approval is required prior to restoring billing privileges.

The Medicare contractor shall process a CAP within 60 days. During this process, the contractor shall not toll the filing requirements associated with an appeal. However, the contractor can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

NOTE: If a CAP and a reconsideration request (i.e., appeal request) are submitted concurrently, the Medicare contractor shall first process and make a determination on the CAP. The reconsideration request should then be processed by a Hearing Officer (HO) unrelated to the initial determination or CAP to ensure the applicant receives an independent review of their reconsideration. The Medicare contractor and the HO shall coordinate prior to acting on a CAP or reconsideration request to determine if the other party has received a request. If the CAP is accepted, the standard approval letter shall be sent to the provider or supplier acknowledging enrollment into Medicare and that their reconsideration request should be withdrawn. If the CAP is denied, the provider or supplier shall be notified by letter and may continue with the appeals process if it has filed a request for reconsideration or is preparing to submit such a request and has not exceeded the timeframe to do so. Providers and suppliers may not appeal a corrective action plan decision.

Reconsideration (formerly Contractor Hearing)

A provider, supplier or DMEPOS supplier that wishes to request a reconsideration must file its request, in writing, with the Medicare contractor within 60 days after the postmark of the notice to be considered timely filed. Medicare contractors shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day of which falls on a weekend or holiday should still be considered timely filed and not rejected. The date the request is received by the Medicare contractor is treated as the date of filing. The request must be signed by the physician, non-physician practitioner, a legal representative, or any responsible authorized official within the entity. For DMEPOS suppliers, the request must be signed by the authorized representative, delegated official, owner or partner. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

Medicare contractor reconsiderations shall be conducted by a HO or senior staff having expertise in provider enrollment and who was independent from the initial decision to deny or revoke enrollment.

The NSC reconsiderations shall be conducted by a HO. All part B certified supplier reconsiderations will be conducted by CMS and shall be forwarded to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

Upon receipt of the reconsideration, the HO shall send a letter to the provider or supplier to acknowledge receipt of their request. In its acknowledgment letter, the HO shall advise the requesting party that the reconsideration will be conducted and a determination issued within 90 days from the date of the request. The HO shall include a copy of its acknowledgment letter in the reconsideration file.

If a timely request for a reconsideration is made, the HO, not involved in the original adverse determination, must hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the HO should limit the scope of its review to the Medicare contractor's reason for imposing a denial or revocation at the time it issued the action and whether the Medicare contractor made the correct decision (i.e., denial/revocation). Medicare contractors cannot introduce new

denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or supplier provides evidence that demonstrates or proves that they met or maintained compliance after the date of denial or revocation, the HO shall exclude this information from the scope of its review.

If a request for reconsideration is filed late, the HO shall make a finding of good cause before taking any other action on the appeal. The time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The HO shall issue a written decision within 90 days from the date of the request and forward the decision to the Medicare contractor and by mail to the provider, supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the HO is upholding or overturning the denial or revocation action in sufficient detail for the provider or supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an administrative law judge (ALJ) hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

If an appeal for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application being appealed. Contractors shall use the receipt date of the appeal as the receipt date they enter in PECOS.

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the Medicare contractor.

When the Medicare contractor receives a withdrawal request, it sends a letter to the provider or supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

Medicare contractors shall maintain a report detailing the number of reconsideration requests they receive and their outcome (e.g., decision withheld, reversed, or further appeal requested or requests withdrawn). Medicare contractors are not required to submit this information to CMS but it must be provided upon request.

Administrative Law Judge (ALJ) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with a reconsidered determination is entitled to a hearing before an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the DAB will issue a letter by certified mail to the provider or supplier, CMS and the regional office of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney that will represent CMS during the appeals process and who will also serve as the DAB point of contact.

Neither CMS nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractors shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

Departmental Appeals Board (DAB) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or supplier dissatisfied with a DAB decision has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

B. Fiscal Intermediary

If a Medicare contractor reviews an initial enrollment application for a provider or certified supplier and finds that the application should be denied pursuant to 42 CFR §424.530, such as a facility's failure to meet one or more of the Federal or State requirements, the Medicare contractor shall deny/recommend denial to the regional office (RO) and notify the provider or certified supplier by letter (see section 14 of this chapter). The denial letter shall contain:

- A legal (i.e., regulatory) basis for each reason for the denial;

- A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;

- Procedures for submitting a corrective action plan (CAP); and

- Complete and accurate information about the provider or supplier's further appeal rights.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or certified supplier's billing privileges, such as the provider or certified supplier no longer meets one of the requirements for billing privileges, the Medicare contractor shall revoke billing privileges and notify the provider or certified supplier by letter with a copy to the State and the RO. The revocation letter must contain:

- A legal (i.e., regulatory) basis for each reason for revocation;

- A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination;

- An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;

- The effective date of the revocation (30 days from the date the notice is mailed. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation);

- Procedures for submitting a CAP; and

- Complete and accurate information about the provider or supplier's further appeal rights.

Corrective Action Plan (CAP)

A CAP is the process that gives the provider or certified supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or certified supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The submission of a CAP for denied or revoked billing privileges must be submitted within 30 days from the date of the notice. The CAP shall contain, at a minimum, verifiable evidence of the provider or certified supplier's compliance with enrollment requirements. CAP requests should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

If a CAP for a denied application or revoked billing privileges is approved by the CMS, billing privileges can be issued. The effective date is based on the date the provider or certified supplier came into compliance with all Medicare requirements. That is, once the provider or certified supplier has passed the state survey and been issued a certification date.

CAP requests will be processed within 60 days. During this process, the CMS will not toll the filing requirements associated with an appeal. However, the CMS can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

Reconsideration

A provider or certified supplier that wishes to request a reconsideration must file its request, in writing, with the CMS within 60 days after the postmark of the notice to be considered timely filed. The request for reconsideration should be sent to:

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

The date the request is received by the CMS is treated as the date of filing. The request may be signed by the authorized official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

If a timely request for a reconsideration is made, the CMS will hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, certified supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or certified supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the CMS will limit the scope of its review to the Medicare contractor/RO's initial reason for imposing a denial or revocation at the time that it issued the action and whether the Medicare contractor/ RO made the correct decision (i.e., denial/revocation). The Medicare contractor/ RO cannot introduce new denial or revocation reasons or change a denial or revocation reason

listed in the initial determination during the reconsideration process. If a provider or certified supplier provides evidence that demonstrates or proves that they met or maintained compliance, after the date of denial or revocation, the CMS will exclude this information from the scope of its review.

If a reconsideration request is filed late, the CMS will make a finding of good cause before taking any other action on the appeal. These time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The CMS will issue a written decision within 90 days from the date of the request and forwards the decision by certified mail to the Medicare contractor, the provider, certified supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including regulatory basis for the action as, determined by the Medicare contractor/ RO in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- A clear explanation of why the CMS is upholding or overturning the denial or revocation action in sufficient detail for the provider or certified supplier to understand the nature of its deficiencies;

- If applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- An explanation of how the provider or certified supplier does not meet the enrollment criteria or requirements to enroll;

- Further appeal rights, procedures for requesting an ALJ hearing, and the address to which the written appeal must be mailed; and

- Information the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the CMS.

When the CMS receives a withdrawal request, it sends a letter to the provider or certified supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

ALJ Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with a reconsidered determination is entitled to a hearing before the ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from the receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request the ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the Departmental Appeals Board (DAB) will issue a letter by certified mail to the provider or certified supplier, CMS, the RO and the RO of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled prehearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and who will also serve as the DAB point of contact. Neither CMS, the RO, nor the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractor shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

DAB Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely

request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or certified supplier dissatisfied with DAB review has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

15.26 – Special Provisions for HHAs

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

15.26.1 – HHA Ownership Changes

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

A. Background

Effective January 1, 2011, and in accordance with 42 CFR §424.550(b)(1) - if there is a change in majority ownership of an HHA by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the provider agreement and Medicare billing privileges do not convey to the new owner. The prospective provider/owner of the HHA must instead:

- Enroll in the Medicare program as a new (initial) HHA under the provisions of §424.510, and

- Obtain a State survey or an accreditation from an approved accreditation organization.

For purposes of §424.550(b)(1), a "change in majority ownership" (as defined in 42 CFR §424.502) occurs when an individual or organization acquires more than a 50 percent direct ownership interest in an HHA during the 36 months following the HHA's initial enrollment into the Medicare program or the 36 months following the HHA's most recent change in majority ownership (including asset sales, stock transfers, mergers, or consolidations). This includes an individual or organization that acquires

majority ownership in an HHA through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the HHA's most recent change in majority ownership.

B. Exceptions

There are several exceptions to §424.550(b)(1). Specifically, the requirements of §424.550(b)(1) do not apply if:

- The HHA has submitted 2 consecutive years of full cost reports. (For purposes of this exception, low utilization or no utilization cost reports do not quality as full cost reports.)

- The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- An individual owner of the HHA dies.

In addition, §424.550(b)(1) does not apply to "indirect" ownership changes.

C. Effective Date

As indicated earlier, the provisions of 42 CFR §424.550(b)(1) and (2) as enacted in "CMS-6010-F, Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices; Final Rule" – are effective January 1, 2011. This means that these provisions impact only those HHA ownership transactions whose effective date is on or after January 1, 2011. However, the provisions can apply irrespective of when the HHA first enrolled in Medicare. Consider the following illustrations:

- Example 1 – Smith HHA initially enrolls in Medicare effective July 1, 2009. Smith undergoes a change in majority ownership effective September 1, 2011. The provisions of §424.550(b)(1) apply to Smith because it underwent a change in majority ownership within 36 months of its initial enrollment.

- Example 2 – Jones HHA initially enrolls in Medicare effective July 1, 2007. Jones undergoes a change in majority ownership effective February 1, 2011. Section 424.550(b)(1) does not apply to this transaction because it occurred more than 36 months after Jones's initial enrollment. Suppose, however, than Jones undergoes another change in majority ownership effective February 1, 2012. Section 424.550(b)(1) would apply to this transaction because it took

place within 36 months after Jones's most recent change in majority ownership (i.e., on February 1, 2011).

- Example 3- Johnson HHA initially enrolls in Medicare effective July 1, 2006. It undergoes a change in majority ownership effective October 1, 2010. This transaction is not affected by §424.550(b)(1) – as enacted in CMS-6010-F – because: (1) its effective date was prior to January 1, 2011, and (2) it occurred more than 36 months after the effective date of Johnson's initial enrollment. Johnson undergoes another change in majority ownership effective October 1, 2012. This change would be affected by §424.550(b)(1) because it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on October 1, 2010).

- Example 4 – Davis HHA initially enrolls in Medicare effective July 1, 1999. It undergoes its first change in majority ownership effective February 1, 2011. This change is not affected by §424.550(b)(1) because it occurred more than 36 months after Davis's initial enrollment. Davis undergoes another change in majority ownership effective July 1, 2014. This change, too, would be unaffected by §424.550(b)(1), as it occurred more than 36 months after the HHA's most recent change in majority ownership (i.e., on February 1, 2011). Davis undergoes another majority ownership change on July 1, 2016. This change would be impacted by §424.550(b)(1), since it occurred within 36 months of the HHA's most recent change in majority ownership (i.e., on July 1, 2014).

D. Section 424.550(b)(1)'s Applicability

If the contractor receives a CMS-855A application reporting an HHA ownership change, it shall undertake the following steps:

1. Step 1 – Change in Majority Ownership

The contractor shall determine whether a change in direct majority ownership has occurred. Through its review of the transfer agreement, sales agreement, bill of sale, etc., the contractor shall verify whether:

- The ownership change was a direct ownership change and not a mere indirect ownership change, and

- The change involves a party assuming a greater than 50 percent ownership interest in the HHA.

Assumption of a greater than 50 percent direct ownership interest can generally occur in one of two ways. First, an outside party that is currently not an owner can purchase more than 50 percent of the business in a single transaction. Second, an existing owner can purchase an additional interest that brings its total ownership stake in the business

to greater than 50 percent. For instance, if a 40 percent owner purchased an additional 15 percent share of the HHA, this would constitute a change in majority ownership. This is consistent with the verbiage in the aforementioned definition of "change in majority ownership" regarding the "cumulative effect" of asset sales, transfers, etc.

If the transfer does not qualify as a change in majority ownership, the contractor can process the application normally. If it does qualify, the contractor shall proceed to Step 2:

2. Step 2 – 36-Month Period

The contractor shall determine whether the effective date of the transfer is within 36 months after the effective date of the HHA's: (1) initial enrollment in Medicare, or (2) most recent change in majority ownership. The contractor shall verify the effective date of the reported transfer by reviewing a copy of the transfer agreement, sales agreement, bill of sale, etc., rather than relying upon the date of the sale as listed on the application. It shall also review its records – and, if necessary, request additional information from the HHA – regarding the effective date of the HHA's most recent change in majority ownership, if applicable.

If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the contractor may process the application normally. If the transfer's effective date falls within one of these timeframes, the contractor shall proceed to Step 3.

3. Step 3 – Applicability of Exceptions

If the contractor determines that a change in majority ownership has occurred within either of the above-mentioned 36-month periods, the contractor shall also determine whether any of the exceptions in §424.550(b)(2) apply. As alluded to earlier, the exceptions are as follows:

a. The HHA has submitted 2 consecutive years of full cost reports.

- For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports. As stated in Pub. 15-2 (Provider Reimbursement Manual, Part 2), section 3204, refer to 42 CFR §413.24(h) for a definition of low Medicare utilization.

- The cost reports must have been: (1) consecutive, meaning that they were submitted in each of the 2 years preceding the effective date of the transfer, and (2) accepted by the contractor.

b. The HHA's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

c. The HHA is changing its existing business structure – such as from a corporation, a partnership (general or limited), or an LLC to a corporation, a partnership (general or limited) or an LLC - and the owners remain the same.

- If the HHA is undergoing a change in business structure other than those which are specifically mentioned in this exemption (e.g., corporation to an LLC), the contractor shall contact its DPSE liaison for guidance.

- For the exemption to apply, the owners must remain the same.

d. An individual owner of the HHA dies – regardless of the percentage of ownership the person had in the HHA.

E. Determination

If the contractor concludes that one of the aforementioned exceptions applies, it may process the application normally. If no exception applies, the contractor shall after first obtaining approval from CMS liaison to do so - send a letter to the HHA notifying it that, as a result of §424.550(b)(1), the HHA must:

- Enroll as an initial applicant; and

- Obtain a new State survey or accreditation after it has submitted its initial enrollment application and the contractor has made a recommendation for approval to the State/RO;

As the new owner must enroll as a new provider, the contractor shall also deactivate the HHA's billing privileges if the sale has already occurred. If the sale has not occurred, the contractor shall alert the HHA that it must submit a CMS-855A voluntary termination application.

F. Additional Notes

The contractor is advised of the following:

1. If the contractor learns of an HHA ownership change by means other than the submission of a CMS-855A application, it shall notify its DPSE liaison immediately.

2. If the contractor determines, under Step 3 above, that one of the §424.550(b)(2) exceptions applies, the ownership transfer still qualifies as a change in majority ownership for purposes of the 36-month clock. To illustrate, assume that an HHA initially enrolled in Medicare effective July 1, 2010. It undergoes a change in majority ownership effective February 1, 2012. The contractor determined that the transaction was exempt from §424.550(b)(1) because the HHA submitted full cost reports in the previous 2 years. On February 1, 2014, the HHA undergoes another change in majority ownership that did not qualify for an exception. The HHA must enroll as a new HHA

under §424.550(b)(1) because the transaction occurred within 36 months of the HHA's most recent change in majority ownership - even though the February 2012 change was exempt from §424.550(b)(1).

15.26.2 – Capitalization

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

A. Background

Effective January 1, 2011, and pursuant to 42 CFR §489.28(a) and §424.510(d)(9), an HHA entering the Medicare program - including a new HHA as a result of a change of ownership if the change of ownership results in a new provider number being issued - must have available sufficient funds, which we term initial reserve operating funds, at (1) the time of application submission, and (2) all times during the enrollment process, to operate the HHA for the three-month period after Medicare billing privileges are conveyed by the Medicare contractor (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

B. Points of Review

At a minimum, the contractor shall verify that the HHA meets the required amount of capitalization:

1. Prior to making its recommendation for approval;

2. After a recommendation for approval is made but before the RO review process is completed;

3. After the RO review process is completed but before the contractor conveys Medicare billing privileges to the HHA; and

4. During the 3-month period after the contractor conveys Medicare billing privileges to the HHA.

The HHA must submit proof of capitalization within 30 calendar days of being requested to do so by the contractor. Should the HHA fail to furnish said proof and billing privileges have not yet been conveyed, the contractor shall deny the HHA's application pursuant to §424.530(a)(8)(i) or (ii), as applicable. If billing privileges have been conveyed, the contractor shall revoke the HHA's billing privileges per §424.535(a)(11).

Should the contractor believe it is necessary to verify the HHA's level of capitalization more than once within a given period, e.g., more than once between the time a recommendation is made and the completion of the RO review process – the contractor

shall seek approval from its DPSE liaison.

C. Determining Initial Reserve Operating Funds

Initial reserve operating funds are sufficient to meet the requirement of 42 CFR §489.28(a) if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of 3 or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first 3 months of operation--or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs--whichever is greater.

The contractor shall determine the amount of the initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least 3 HHAs that the contractor serves that are comparable to the HHA that is seeking to enter the Medicare program. Factors to be used in making this determination shall include:

- Geographic location and urban/rural status;
- Number of visits;
- Provider-based versus free-standing status; and
- Proprietary versus non-proprietary status.

The determination of the adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first 3 months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a 3-month period for the HHAs used in determining the average cost per visit.

D. Proof of Operating Funds

The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, must include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA.

In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the

purpose of this section are Treasury bills, commercial paper, and money market funds.

As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS may later require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds constitutes non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

E. Borrowed Funds

If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

F. Line of Credit

If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

G. Documents

As part of ensuring the prospective HHA’s compliance with the capitalization requirements, the contractor shall obtain the following from the provider:

- A document outlining the provider’s projected budget – preferably, a full year’s budget broken out by month

- A document outlining the number of anticipated visits - preferably a full year broken out by month

- An attestation statement from an officer of the HHA defining the source of funds

- Copies of bank statements, certificates of deposits, etc., supporting that cash is available (must be current)

- Letter from officer of the bank attesting that funds are available

- If available, audited financial statements

The contractor shall also ensure that the capitalization information in section 12, of the CMS-855A is provided.

15.27 – Deactivations and Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If circumstances warrant, a fee-for-service contractor shall deactivate or revoke a provider or supplier's Medicare billing privileges under certain circumstances. Deactivation or revocation of Medicare billing privileges will not impact a provider or supplier's ability to submit claims to non-Medicare payers using their National Provider Identifier.

27.1 – CMS or Contractor Issued Deactivations

(Rev. 362, Issued: 12-17-10, Effective: 01-01-11, Implementation: 01-01-11)

A. General Instructions

The contractor may deactivate a provider or supplier's Medicare billing privileges when:

- A provider or supplier does not submit any Medicare claims for 12 consecutive calendar months. The 12 month period begins on the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim;

- A provider or supplier fails to report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services; or

- A provider or supplier fails to report a change in ownership or control within 30 calendar days.

The deactivation of Medicare billing privileges does not affect a supplier's participation agreement (CMS-460).

Providers and suppliers deactivated for non-submission of a claim are required to

complete and submit a Medicare enrollment application to recertify that the enrollment information currently on file with Medicare is correct and must furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation.

Providers and suppliers that fail to promptly notify the contractor of a change (as described above) must submit a complete Medicare enrollment application to reactivate their Medicare billing privileges or, when deemed appropriate, recertify that the enrollment information currently on file with Medicare is correct. Reactivation of Medicare billing privileges does not require a new State survey or the establishment of a new provider agreement or participation agreement. However, per 42 CFR §424.540(b)(3)(i), and as described in subsection E below, an HHA whose billing privileges are deactivated must undergo a State survey or obtain accreditation prior to having its billing privileges reactivated.

Each contractor shall forward a copy of the Deactivation Summary Report provided by the Multi-Carrier System (MCS) to its designated DPSE contractor liaison no later than the last calendar day of each month.

B. Special Reactivation Instructions for Part B Suppliers

(This section does not apply to: (1) providers and suppliers that complete the CMS-855A application, and (2) DMEPOS suppliers.)

To ensure that a supplier that has reactivated its Medicare billing privileges does not become subject to a second deactivation for non-billing within 30 days of the reactivation, the contractor shall:

1. End-date the existing PTAN-NPI combination in sections 1 and 4 of PECOS with the non-billing end-date in MCS, and

2. Issue a new Provider Transaction Access Number (PTAN) to the provider or supplier, and associate the new PTAN with the NPI in sections 1 and 4 of PECOS.

For physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians or nutrition professionals, or organizations (e.g., group practices) consisting of any of the aforementioned categories of individuals, the contractor shall establish the reactivation effective date as the later of: (a) the filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor, or (b) the date the supplier first started furnishing services at a new practice location.

The exception to this is if the supplier has at least one other enrolled practice location (under the same TIN) for which it is actively billing Medicare; here, the contractor shall establish and enter the effective date as either: (a) the date the supplier first saw a

Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS, whichever is later. To illustrate, if the supplier has only one enrolled practice location and that site is deactivated for non-billing, the effective date is the later of: (a) the filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor, or (b) the date the supplier first started furnishing services at a new practice location. On the other hand, suppose the supplier has two enrolled locations – X and Y - under its TIN. Location X is actively billing Medicare, but Y is deactivated for non-billing. The reactivation effective date for Y would be the later of: (a) the date the supplier first saw a Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS. This is because the supplier has at least one other location – Location X – that is actively billing Medicare.

For individual and organizational suppliers other than those identified in the beginning of the previous paragraph, the contractor shall enter the effective date as either: (a) the date the supplier first saw a Medicare patient at the location indicated on the CMS-855, or (b) the same date as the non-billing end-date in MCS, whichever is later.

If the supplier's PTAN is only established in MCS, no action is required if the end-dated non-billing number is not in PECOS.

C. DMEPOS Deactivation

The NSC shall require a DMEPOS supplier whose billing privileges are deactivated for non-submission of claims (see CFR 42 CFR §424.540) to submit a new Medicare enrollment application and meet all applicable enrollment criteria, including a site visit, and accreditation when applicable, before an applicant can be approved. The NSC may not establish a retrospective billing date for a DMEPOS supplier whose billing privileges were deactivated due to claims inactivity.

D. Deactivation and Appeals Rights

The Medicare contractor shall not afford a provider or supplier appeal rights when a deactivation determination is made.

E. HHA Reactivations

Pursuant to 42 CFR §424.540(b)(3), if an HHA's billing privileges are deactivated under 42 CFR §424.540(a), the HHA must undergo a State survey or obtain accreditation in order for its billing privileges to be reactivated. If a deactivated HHA submits a CMS-855A reactivation application, the contractor shall process the application normally and either: (1) recommend approval to the State, or (2) deny the application. If a recommendation for approval is made to the State, the contractor shall:

- Switch the HHA's PECOS record to an "Approval Recommended" status;

- Send a copy of the HHA's application, along with a recommendation letter, to the State agency;

- Explain in its recommendation letter to the State that the application was for a reactivation of billing privileges and that, pursuant to 42 CFR §424.540(b)(3), a State survey or accreditation is required. (A copy of the letter should be sent to the RO.)

- Notify the HHA (via e-mail or letter) of both the recommendation of approval and the requirement in 42 CFR §424.540(b)(3). The contractor shall also alert the HHA that it must: (1) pass the State/accreditation survey and (2) submit written proof that it did so, to the contractor prior to having its billing privileges reactivated.

NOTE: The contractor will not receive a tie-in notice or approval letter from the RO. It can switch the PECOS record to "Approved" once the HHA submits the documentation described in item (2) of the previous bullet; the effective date of billing shall be the date on which the contractor switches the PECOS record to "Approved."

15.27.2 – Contractor Issued Revocations

(Rev. 353, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

A. Revocation Reasons

The contractor may issue a revocation using revocation reasons 1 through 11 below without prior approval from CMS. Sections 27.3 through 27.3.2 below address revocation reason 12 (42 CFR §424.535(a)(8)), which requires DPSE review and approval.

When issuing a revocation, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.535(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter as the basis for revocation.

Revocations based on non-compliance:

Revocation 1 (42 CFR §424.535(a)(1))

The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section or in the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR Part 488.

Noncompliance includes, but is not limited to the provider or supplier no longer having a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider or other person and/or the provider or supplier no longer meets or maintains general enrollment requirements. Noncompliance also includes situations when the provider or supplier has failed to pay any user fees as assessed under 42 CFR Part 488.

Revocation 2

The provider or supplier has lost its license(s) or is not authorized by the Federal/state/local government to perform the services for which it intends to render. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with.)

Revocation 3

The provider or supplier no longer meets CMS regulatory requirements for the specialty for which it has been enrolled. (In its revocation letter, the contractor shall cite the appropriate statutory and/or regulatory citations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the revocation letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with.)

Revocation 4 (42 CFR §424.535(a)(1))

The provider or supplier (upon discovery) does not have a valid SSN/employer identification number for itself, an owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

Revocations based on provider or supplier conduct:

Revocation 5 (42 CFR §424.535(a)(2))

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is:

(i) Excluded from the Medicare, Medicaid, and any other Federal health care program, as defined in 42 CFR §1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(ii) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

If an excluded party is found, notify DPSE immediately. DPSE will notify the

Government Task Leader (GTL) for the appropriate PSC. The GTL will, in turn, contact the Office of Inspector General's office with the findings for further investigation.

Revocations based on felony:

Revocation 6 (42 CFR §424.535(a)(2))

The provider, supplier, or any owner of the provider or supplier, within the 10 years preceding enrollment or revalidation of enrollment, was convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries to continue enrollment.

(i) Offenses include—

(A) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(C) Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(D) Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

(ii) Revocations based on felony convictions are for a period to be determined by the Secretary, but not less than 10 years from the date of conviction if the individual has been convicted on one previous occasion for one or more offenses.

The Centers for Medicare & Medicaid Services (CMS) stresses, however, that an enrollment bar issued pursuant to 42 CFR §424.535(c) does not preclude CMS or its contractors from denying re-enrollment to a provider or supplier who was convicted of a felony within the preceding 10-year period or who otherwise does not meet all criteria necessary to enroll in Medicare.

Revocations based on false or misleading information:

Revocation 7 (42 CFR §424.535(a)(4))

The provider or supplier certified as ‘‘true’’ misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program.

(Offenders may be subject to either fines or imprisonment, or both, in accordance with current laws and regulations.)

Revocations based on misuse of billing number

Revocation 8 (42 CFR §424.535(a)(7))

The provider or supplier knowingly sells to or allows another individual or entity to use its billing number. This does not include those providers or suppliers who enter into a valid reassignment of benefits as specified in 42 CFR §424.80 or a change of ownership as outlined in 42 CFR § 489.18.

Additional revocation reasons:

Revocation 9 (42 CFR §424.535(a)(5))

The CMS determines, upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients. Upon on-site review, CMS determines that—

(i) A Medicare Part A provider is no longer operational to furnish Medicare covered items or services, or the provider fails to satisfy any of the Medicare enrollment requirements.

(ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

Revocation 10 (42 CFR §424.535(a)(6))

The provider or supplier fails to furnish complete and accurate information and all supporting documentation within 30 calendar days of the provider or supplier's notification from CMS to submit an enrollment application and supporting documentation.

Revocation 11 (42 CFR §424.535(a)(9))

The physician, non-physician practitioner, physician organization or non-physician organization failed to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii) or (iii), which pertain to the reporting of changes in adverse actions and practice locations, respectively, within 30 days of the reportable event.

Note the following with respect to Revocation 11:

- This revocation reason only applies to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; registered dietitians or nutrition professionals, and organizations (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph.

- If the individual or organization reports a change in practice location more than 30 days after the effective date of the change, the contractor shall not revoke the supplier's billing privileges on this basis. However, if the contractor independently determines – through an on-site inspection under 42 CFR 424.535(a)(5)(ii) or via another verification process - that the individual's or organization's address has changed and the supplier has not notified the contractor of this within the aforementioned 30-day timeframe, the contractor may revoke the supplier's billing privileges.

B. Effective Date of Revocations

Per 42 CFR §405.874(b)(2), a revocation is effective 30 days after CMS or the CMS contractor (including the NSC) mails the notice of its determination to the provider or supplier. However, per 42 CFR §424.535(g) a revocation based on a: (1) Federal exclusion or debarment, (2) felony conviction as described in 42 CFR §424.535(a)(3), (3) license suspension or revocation, or (4) determination that the provider or supplier is no longer operational, is effective with the date of the exclusion, debarment, felony conviction, license suspension or revocation, or the date that CMS or the contractor determined that the provider or supplier is no longer operational.
Note that in accordance with CFR §424.565, if an individual or organization identified in section 7.1(A) of this chapter fails to comply with the reporting requirements specified in 42 CFR §424.516(d)(1)(ii), the contractor may assess an overpayment back to the date of the final adverse action, though said date shall be no earlier than January 1, 2009. Moreover, no later than 10 calendar days after the contractor assesses the overpayment, the contractor shall notify its DPSE liaison of the amount assessed.

As stated in 42 CFR §424.535(d), if the revocation was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services and/or supplies, the revocation may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the revocation notification. The contractor, however:

- Need not solicit or ask for such proof in its recommendation letter. It is up to the provider/supplier to furnish this data on its own volition.

- Has the ultimate discretion to determine whether sufficient "proof" exists.

C. Payment

Per 42 CFR §405.874(b)(3), Medicare does not pay and a CMS contractor rejects claims for items or services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

D. Reapplying After Revocation

As stated in 42 CFR §424.535(c), after a provider, supplier, delegated official, or authorizing official that has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar.

Unless stated otherwise in this section, the re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation. The contractor shall establish the re-enrollment bar in accordance with the following:

1 year (AR 73) – License revocation/suspension that a deactivated provider (i.e., is enrolled, but is not actively billing) failed to timely report to CMS; provider failed to respond to revalidation request.

2 years (AR 74) – The provider is no longer operational.

3 years (AR 81) – Medical license revocation/suspension and the practitioner continued to bill Medicare after the license revocation/suspension; felony conviction and the practitioner continued to bill Medicare after the date of the conviction; falsification of information.

For all other revocation reasons, the contractor shall contact its DPSE liaison; DPSE will establish the appropriate enrollment bar for that particular case.

The contractor shall update PECOS to reflect that the individual is prohibited from participating in Medicare for the 1, 2, or 3-year period reflected by the enrollment bar in question.

Note also that reenrollment bars apply only to revocations. The contractor shall not impose a reenrollment bar following a denial of an application.

E. Submission of Claims for Services Furnished Before Revocation

Per 42 CFR §424.535(g), any physician, physician assistants, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietitian or nutrition professional, organization (e.g., group practices) consisting of any of the categories of individuals identified in this paragraph, or IDTF who/that is revoked from the Medicare program must, within 60 calendar of the effective date of the revocation, submit all claims for

items and services furnished.

F. Reporting of Final Adverse Action - Compliance

If a physician or non-physician practitioner reports the imposition of a final adverse action (other than felony convictions) against him or her within the reporting timeframes specified in 42 CFR §424.516, and if the final adverse action is one for which the provider's billing privileges would typically be revoked, the contractor shall:

- Treat the submission as a voluntary withdrawal, rather than a revocation; and

- Establish an overpayment back to the date of the reportable event if the practitioner furnished services after the reportable event.

By reporting final adverse actions in a timely manner (i.e., 30 days), physicians and non-physician practitioners can avoid the imposition of an enrollment bar.

(As alluded to above, this policy does not apply to felony convictions. The contractor must revoke the provider's billing privileges in such cases even if the provider timely reported the conviction.)

(For purposes of this section, the term non-physician practitioner only includes physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives; clinical social workers; clinical psychologists; and registered dietitians or nutrition professionals.)

G. Notification to Other Contractors

If the contractor revokes a provider or supplier's Medicare billing privileges, the contractor shall determine, via a search of PECOS, whether the provider/supplier is enrolled with any other Medicare contractors. If the contractor determines that the revoked provider/supplier is indeed enrolled with another contractor(s), the revoking contractor shall notify these other contractors of the revocation; the notification shall be done via e-mail and shall contain a short description of the reason for the revocation.

Upon receipt of this notification from the revoking contractor, the receiving contractor shall determine whether the provider or supplier's billing privileges should be revoked in its jurisdiction as well. Should the contractor need assistance in making this determination, it may contact its DPSE liaison or BFL.

H. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 19 of this chapter.

I. Summary

If the contractor determines that a provider's billing privileges should be revoked, it shall undertake the activities described in this section, which include, but are not limited to:

- Revoking the provider's billing privileges back to the appropriate date;
- Establishment of the applicable reenrollment bar;
- Updating PECOS to show the length of the reenrollment bar;
- Assessment of an overpayment, as applicable;
- Providing DPSE with the amount of the assessed overpayment within 10 days of the overpayment assessment; and
- Affording appeal rights.

J. Reporting Revocations/Terminations to the State Medicaid Agencies and Child Health Plans

No later than the 5th of each month contractors shall notify CMS, which will in turn notify the State Medicaid agencies and child health plans of Medicare revocations due to felony adverse actions and non compliance (i.e., non operational, loss of license) and Medicare terminations of provider agreements for certified provider and suppliers by sending a report to Medicare_terminations@cms.hhs.gov. Contractors shall use the supplied spreadsheet and include the following information:

- Legal name or legal business name;
- National provider identifier (NPI);
- Correspondence or practice location;
- Reason for revocation/termination;
- Date of revocation/termination; and
- Length of re-enrollment bar (if applicable).

The first report is due on September 5, 2010, and shall contain revocations/terminations from March 23 – August 31, 2010. Thereafter, reports shall be submitted by the 5th of each month to the designated CMS mailbox. If there are no revocations/terminations to report for the month contractors shall send an email to the mailbox indicating a negative report.

27.2.1 - Revocations Involving Certified Suppliers and Providers

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If the contractor determines that one or more of the revocation reasons identified in section 27.2 of this manual are applicable, the contractor may revoke the billing privileges of a certified provider or certified supplier without making a recommendation for approval or denial to the State and RO. It can, in other words, revoke billing privileges at the contractor level. However, as indicated in section 27.2, the contractor

shall first notify DPSE prior to initiating any revocation action.

In revoking the provider or supplier, the contractor shall:

- Issue the revocation letter in accordance with section 27.2; the contractor shall copy the RO and/or the State on said letter;

- After determining the effective date of the revocation, end-date the entity's enrollment record in PECOS in the same manner as it would upon receipt of a tie-out notice from the RO.

- Afford the appropriate appeal rights per section 19 of this manual.

27.3 - DPSE Issued Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Based on information from a Program Safeguard Contractor (PSC), CMS satellite office, or other CMS component, including a regional office, DPSE may request that fee-for-service contractors revoke a provider or supplier's Medicare billing privileges using revocation 12. Fee-for-service contractors shall only issue a revocation using Revocation 12 when they receive a properly executed Joint Signature Memorandum from CMS.

27.3.1 - PSC Identified Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If a PSC believes that the use of revocation 12 is appropriate, the PSC will develop a case file, including their reason(s) for revocation, and submit the case file and all supporting documentation to their respective government task leader (GTL). The PSC will provide the GTL with the name, all known billing numbers, including the NPI and associated Medicare billing numbers, and locations of the provider or supplier in question as well as detailed information to substantiate the revocation action.

The GTL will review the PSC case file and:

- Return the case file to PSC for additional development, or
- Recommend that DPSE consider approval the PSC recommendation for revocation.

If DPSE concurs with GTL's revocation recommendation, DPSE will instruct the applicable fee-for-service contractor to revoke a billing number through a Joint Signature Memorandum and notify the DBIMO of the action taken.

27.3.2 - CMS Satellite Office or Regional Office Identified Revocations

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If a CMS satellite office or regional office believes that the use of revocation 12 (see 42 is appropriate, the CMS satellite office or regional office will develop a case file, including the reason(s) for revocation, and submit the case file and all supporting documentation to DPSE. The CMS satellite office or regional office will provide the DPSE with the name, all known billing numbers, including the NPI and associated Medicare billing numbers, and locations of the provider or supplier in question as well as detailed information to substantiate the revocation action.

If DPSE concurs with revocation recommendation, DPSE will instruct the applicable contractor to revoke the billing number and notify DBIMO of the action taken.

Revocation 12 (42 CFR §424.535(a)(8))

The provider, supplier or DMEPOS supplier submits a claim or claims for services or supplies that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

27.4 - External Reporting Requirements

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

No later than the last day of January, April, July and October of each year, the contractor shall furnish to its DPSE liaison via e-mail the following information for the previous quarter:

A. Fiscal Intermediaries (includes A/B MACs)

- Number of recommendations for denial of initial CMS-855A applications (including new owner CHOWs) and the three most frequent reasons for said recommendations;

- Number of revocations (or recommendations for revocations) and the three most frequent reasons for said actions.

B. Carriers (includes A/B MACs)

- Number of denials of initial CMS-855 applications (this includes denial recommendations for ASCs and PXRS) and the three most frequent reasons for said denials. (CMS-855B and CMS-855I denials shall be listed separately.)

- Number of revocations and the three most frequent reasons therefore. (CMS-855B and CMS-855I revocations shall be listed separately.)

The contractor need not submit this data to CMS via any sort of spreadsheet. A simple

e-mail is sufficient. The first report is due by January 31, 2008, and shall cover actions taken in October, November and December of 2007.

15.28 – Deceased Practitioners

(Rev. 357, Issued: 10-01-10, Effective: 10-01-10, Implementation: 10-04-10)

A. Reports of Death from the Social Security Administration (SSA)

Contractors, including DME MACs and the NSC MAC, will receive from CMS a monthly file that lists individuals who have been reported as deceased to the SSA. To help ensure that Medicare maintains current enrollment and payment information and to prevent others from utilizing the enrollment data of deceased individuals, the contractor shall undertake the activities described below.

B. Verification Activities

1. Individuals Other than Physicians, Non-Physician Practitioners and/or Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

If the person is an owner, managing employee, director, officer, authorized official, etc., the contractor shall verify and document that the person is deceased using the verification process described in 16(B) above.

Once the contractor verifies the report of death, it shall notify the provider or supplier organization with whom the individual is associated that it needs to submit a CMS-855 change request that deletes the individual from the provider or supplier's enrollment record. If a provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's Medicare billing privileges in accordance with 42 CFR §424.540(a)(2). DMEPOS Suppliers Only - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with 42 CFR § 424.57(c)(2).

The contractor need not, however, solicit a CMS-855 change request if:

- The associate was the sole owner of his or her professional corporation or professional association. The contractor can simply terminate that organization's enrollment in Medicare and then undertake all actions normally associated with a termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

- The organization is enrolled with another contractor. Here, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16.

C. Reports of Death from Third-Parties

If a contractor, including DME MACs or the NSC MAC, receives a report of death from a third-party (State provider association, State medical society, academic medical institution, etc.), the contractor shall verify that the individual practitioner, non-physician practitioner or DMEPOS supplier is deceased by:

- Obtaining oral or written confirmation of the death from an authorized or delegated official of the group practice to which the individual practitioner, non-physician practitioner or DMEPOS supplier had reassigned his or her benefits; or

- Obtaining an obituary notice from the newspaper; or

- Obtaining oral or written confirmation from the State licensing board (e.g., telephone, e-mail, computer screen printout); or

- Obtaining oral or written confirmation from the State Bureau of Vital Statistics; or

- Obtaining a death certificate, Form SSA-704, or Form SSA-721 (Statement of Funeral Director).

Once the contractor verifies the death, it shall:

1. Undertake all actions normally associated with the termination of a supplier's billing privileges, with the exception of sending a termination letter to the practitioner, non-physician practitioner or DMEPOS supplier.

2. Search PECOS to determine whether the individual is listed therein as an owner, managing employee, director, officer, partner, authorized official, or delegated official.

3. If the person <u>is not</u> in PECOS, no further action with respect to that individual is needed.

4. If the supplier is indeed identified in PECOS as an owner, officer, etc., the contractor shall notify the organization with whom the person is associated that it needs to submit a CMS-855 change request that deletes the individual from the entity's enrollment record. If a provider fails to submit this information within 90 calendar days of the contractor's request, the contractor shall deactivate the provider's billing privileges in accordance with 42 CFR §424.540(a)(2). DMEPOS Suppliers Only - If a DMEPOS supplier fails to submit this information within 30 calendar days of the contractor's request, the contractor shall deactivate the supplier's billing privileges in accordance with 42 CFR § 424.57(c)(2).

The contractor need not, however, ask for a CMS-855 change request if:

a. The practitioner, non-physician practitioner or DMEPOS supplier was the sole owner of his/hers professional corporation or professional association. The contractor can simply terminate the organization's enrollment in Medicare. It shall then undertake all termination actions normally associated with the termination of a supplier's billing privileges, including sending a termination letter to the supplier; or

b. The organization is enrolled with another contractor. In this situation, the contractor shall notify (via fax or e-mail) the contractor with which the organization is enrolled of the situation, at which time the latter contractor shall take actions consistent with this section 16.

The contractor shall place verification documentation in the provider or supplier file in accordance with section 10 of this chapter.

D. Education & Outreach

Contractors, including DME MACs and the NSC MAC, shall conduct outreach to State provider associations, State medical societies, academic medical institution, and group practices, etc., regarding the need to promptly inform contractors of the death physicians, non-physician practitioners participating in the Medicare program.

E. Trustees/Legal Representatives

1. NPI - The trustee/legal representative of a deceased provider, non-physician practitioner or DMEPOS supplier's estate may deactivate the NPI of the deceased provider by providing written documentation to the NPI enumerator.

2. Special Payment Address - In situations where an individual practitioner, non-physician practitioner or DMEPOS supplier has died, the contractor can make payments to the individual's estate per the instructions in Pub. 100-04, chapter 1. When the contractor receives a request from the trustee or other legally-recognized representative of the provider, non-physician practitioner or DMEPOS supplier's estate to change the provider, non-physician practitioner or DMEPOS supplier's special payment address, the contractor shall, at a minimum, ensure that the following information is furnished:

- CMS-855 change of information request that updates the "Special Payment" address in the application. The CMS-855 can be signed by the trustee/legal representative.

- Any evidence – within reason - verifying that the practitioner, non-physician practitioner or DMEPOS supplier is in fact deceased.

- Legal documentation verifying that the trustee/legal representative has the legal authority to act on behalf of the provider, non-physician practitioner or DMEPOS supplier's estate.

The policies in this section 16(E)(1) and (2) apply only to individual practitioners, non-physician practitioners and DMEPOS suppliers who operated their business as sole proprietors. It does not apply to solely-owned corporations, limited liability companies, etc., nor does it apply to situations in which the practitioner, non-physician practitioner or DMEPOS supplier reassigned his or her benefits to another entity.

29 - Provider and Supplier Revalidations and DMEPOS Re-enrollment

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

Per 42 CFR § 424.515, Medicare providers and suppliers (other than DMEPOS suppliers) must resubmit and recertify the accuracy of their enrollment information every five years in order to maintain Medicare billing privileges. Contractors may initiate revalidation activities at any time during the fiscal year.

The following principles apply to revalidation:

- The processing times for "initial" applications – outlined in section **6**.1 of this manual – apply to revalidation applications.

- Per 42 CFR § 424.515, a provider whom the contractor requested to furnish all requested information (as part of the revalidation) must do so within 60 calendar days after the date the contractor notified the provider of the need to revalidate. If the provider fails to do so, the contractor shall revoke the provider's billing privileges using existing revocation procedures.

- The provider must submit all required documentation with its application, even if such documentation is already on file with the contractor.

The contractor shall verify all data furnished on the application – just as it would with an initial enrollment – using the procedures identified in this manual (e.g., section 8.2)

29.1 - Supplementary Revalidation Activities

(Rev. 354, Issued: 08-27-10, Effective: 09-28-10, Implementation: 09-28-10)

If, as of the last day of the eighth month of the fiscal year for legacy contractors (May 31) or the current contract year for A/B MAC contractors, the contractor's provider enrollment workload and costs are both less than what was projected to CMS at the beginning of the fiscal/contract year, the contractor shall undertake revalidation efforts commensurate with the amount of surplus funding. In doing so, the contractor shall first revalidate those providers that do not have an established enrollment record in PECOS.

Revalidation of the remaining providers shall be conducted in roughly the following order:

1. Providers that have not updated their enrollment information within the previous 5

years (i.e., have not submitted a CMS-855 change of information within that time span).

2. High-risk providers (e.g., provider is located in a historically high-risk metropolitan area or is of a high-risk provider/supplier type).

3. Providers that are not receiving payments via EFT.

4. High-reimbursement providers.

15.31 - Provider Enrollment Fraud Detection Program for High Risk Areas

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

The PSCs shall identify an area as a potential high risk for provider/supplier enrollment and shall notify the A/B MACs and ACs, excluding the NSC, through the JOA process. High risk areas may be identified by emerging or widespread anomalies that may lead to potential fraud and abuse in, for example, claim type, provider type and geographic area. (See PIM, chapter 4, §§4.32 and 4.32.1 for additional information concerning the responsibilities of the PSC.)

After receiving and reviewing the information on the potential high risk areas the AC or the A/B MAC shall determine if the information is a high risk for provider/ supplier enrollment and, if so, provide a written request to the Director of the Division of Provider and Supplier Enrollment (DPSE), requesting approval that the area be designated as high risk. The request should include the name of the AC or the A/B MAC, a contact name, phone number and a justification for designating an area as high risk for fraud and abuse.

The A/B MAC shall notify its project officer of the request for designation as a high risk fraud and abuse area concurrent with the A/B MAC's request for approval to the Director of DPSE.

15.31.1 – Submission of Proposed Implementation Plan for High Risk Areas

(Rev. 356, Issued: 09-24-10, Effective: 10-26-10, Implementation: 10-26-10)

Upon obtaining approval from the Director of the DPSE within the Program Integrity Group regarding the designation of a high risk area, the A/B MAC or AC shall submit, for approval, an implementation plan that addresses the problems identified in the high risk areas. The request shall include the name of the A/B MAC or AC, a contact name, phone number, and a description of the proposed action plan.

The A/B MAC or AC shall propose an implementation plan that includes, but is not limited to the following actions to remediate the identified problems in the high areas:

- Conduct revalidation activities;

- Conduct unannounced site visits;
- Expand verification and validation activities to include felony searches for individuals, owners, managing officials, and delegated officials;
- Establish a risk assessment for newly enrolled providers/suppliers.

The A/B shall work with its project officer in coordination with DPSE to determine the specific support functions needed for ongoing and proposed project activities.

If the A/B MAC or AC determines that a provider or supplier no longer meets Medicare enrollment standards, the MAC or AC shall follow the procedures set forth in section 13 of this chapter.

15.34 – Customer Service/Outreach

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.1 - Web Sites

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors must provide a link to CMS' provider/supplier enrollment Web site located at http: www.cms.hhs.gov/MedicareProviderSupEnroll. The link shall be available on the contractor's existing provider outreach Web site (which should be an established subdomain of the contractor's current commercial Web site) and it must comply with the guidelines stated in the Provider/Supplier Information and Education Web site section (Activity Code 14101) under the Provider Communications (PCOM) Budget and Performance Requirements (BPRs). Bulletins, newsletters, seminars/workshops and other information concerning provider enrollment issues shall also be made available on the existing provider outreach Web site. All contractor Web sites must comply with section 508 of the Rehabilitation Act of 1973 in accordance with, 36 CFR §1194, and must comply with CMS' Contractor Web site Standards and Guidelines posted on CMS's Web site.

The CMS Provider/Supplier Enrollment Web site, http://www.cms.hhs.gov/ MedicareProviderSupEnroll, furnishes the user with access to provider/supplier enrollment forms, specific requirements for provider/supplier types, manual instructions, frequently asked questions (FAQs), contact information, hot topics, and other pertinent provider/supplier information. The contractor shall not duplicate content already provided at the CMS provider/supplier enrollment Web site, and shall not reproduce the forms or establish the contractor's own links to forms. It shall, however, have a link on its Web site that goes directly to the forms section of the CMS provider/supplier enrollment site.

On a quarterly basis, each contractor shall review and provide updates regarding their information that we show at URL:
http://www.cms.hhs.gov/MedicareProviderSupEnroll/downloads/contact_list.pdf
If the contractor services several States with a universal address and telephone number, the contractor shall report that information. In situations where no actions are required,

a response from the contractor is still required (i.e., the contact information is accurate). In addition, only information that pertains to provider enrollment activity for the contractor's jurisdiction is to be reported. All updates shall be sent directly via e-mail to the contractor's assigned DPSE liaison or Business Function Lead (BFL.)

15.34.2 - Provider Enrollment Inquiries

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor's customer service unit may handle provider enrollment inquiries that do not involve complex enrollment issues. Examples of inquiries that can be processed by customer service units include:

- Application status checks (e.g., "Has the contractor finished processing my application?");

- Furnishing information on where to access the CMS-855 forms (and other general enrollment information) on-line;

- Explaining to providers/suppliers which CMS-855 forms should be completed.

- Contractors may wish to consider establishing electronic mechanisms by which providers can obtain updates on the status of their enrollment applications via the contractor's Web site or via automated voice response (AVR).

Contractors are strongly encouraged to establish e-mail "listserves" with the provider community to disseminate important information thereto, such as contractor address changes, new CMS enrollment policies or internal contractor procedures, reminders about existing policies, etc. By being proactive in distributing information to their providers on a regular basis (e.g., weekly, bi-weekly), contractors can reduce the number of policy inquiries they receive and help facilitate the submission of complete and accurate CMS-855 applications.

15.34.3 – Mailing Annual "Supplier Responsibilities" Letter

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.1 – Mailing Annual Material to Physicians

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.2 – Mailing Annual Material to Non-physician Sole Practitioners

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.34.3.3 – Mailing Annual Material to Physicians and Non-physician Practitioner Organizations

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.36 – Document Retention

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

15.36.1 – Security
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

The contractor shall ensure that the highest level of security is maintained for all systems and its physical and operational processes, in accordance with the CMS/Business Partners Systems Security Manual (BPSSM) and the Program Integrity Manual.

Applications shall never be removed from the controlled area to be worked on at home or in a non-secure location. Additionally, provider enrollment staff must control and monitor all applications accessed by other contractor personnel.

All contractor staff shall be trained on security procedures as well as relevant aspects of the Privacy Act and the Freedom of Information Act. This applies to all management, users, system owners/managers, system maintainers, system developers, operators and administrators, including contractors and third parties, of CMS information systems, facilities, communication networks and information.

Note that these instructions are in addition to, and not in lieu of, all other instructions issued by CMS regarding security.

15.36.2 - Release of Information
(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

On October 13, 2006, CMS published System of Records Notice for the Provider Enrollment, Chain and Ownership System (PECOS) in the Federal Register. Consistent with this notice, once the provider has submitted an enrollment application (as well as after it has been enrolled), the contractor shall not release – either orally or in writing - provider-specific data to any other person or entity. This includes, but is not limited to, national or State medical associations or societies, clearinghouses, billing agents, provider associations, or any person within the provider's organization other than the provider's authorized official (section 15 of the CMS-855), delegated official (section 16) or contact person (section 13). The only exceptions to this policy are:

- A routine use found in the aforementioned System of Records applies;

- The provider (or, in the case of an organizational provider, an authorized or delegated official): (1) furnishes a signed written letter on the provider's letterhead stating that the release of the provider data is authorized, and (2) the contractor has no reason to question the authenticity of the person's signature.

- The release of the data is specifically authorized in some other CMS instruction or directive.

(These provisions also apply in cases where the provider requests a copy of any CMS-

855 paperwork the contractor has on file.)

It is recommended that the contractor notify the provider of the broad parameters of the aforementioned policy as early in the enrollment process as possible.

In addition:

- When sending e-mails, the contractor shall not transmit sensitive data, such as SSNs or EINs.

- The contractor may not send PECOS screen printouts to the provider.

- Carriers shall not send Medicare provider numbers (PINs) to groups or organizations, including the group's authorized or delegated official. If a group/organization needs to know the PIN number of an individual provider, it must contact the provider directly for this information or have the individual provider request this information in writing from the carrier. If the individual provider requests its PIN number, the carrier can mail it to the provider's practice location. The contractor should never give this information over the phone.

15.36.3 – File Maintenance

(Rev. 347, Issued: 07-15-10, Effective: 07-30-10, Implementation: 07-30-10)

Contractors shall maintain and store all documents relating to the enrollment of a provider into the Medicare program. These documents include, but are not limited to, Medicare enrollment applications and all supporting documents, attachments, correspondence, and appeals submitted in conjunction with an initial enrollment, reassignment, change of enrollment, revalidation, etc.

Supporting documentation includes, but is not limited to:

- Copies of Federal, State and/or local (city/county) professional licenses, certifications and/or registrations;

- Copies of Federal, State, and/or local (city/county) business licenses, certifications and/or registrations;

- Copies of professional school degrees or certificates or evidence of qualifying course work; and

- Copies of CLIA certificates and FDA mammography certificates.

Medicare contractors shall dispose of the aforementioned records as described below:

1) Provider/Supplier and Durable Medical Equipment Supplier Application

a. Rejected applications as a result of provider failing to provide additional information

Disposition: Destroy when 7 years old.

b. Approved applications of provider/supplier

Disposition: Destroy 15 years after the provider/supplier's enrollment has ended.

c. Denied applications of provider/supplier.

Disposition: Destroy 15 years after the date of denial.

d. Approved application of provider/supplier, but the billing number was subsequently revoked.

Disposition: Destroy 15 years after the billing number is revoked.

e. Voluntary deactivation of billing number

Disposition: Destroy 15 years after deactivation.

f. Provider/Supplier dies

Disposition: Destroy 7 years after date of death.

2) Electronic Mail and Word Processing System Copies

a. Copies that have no further administrative value after the recordkeeping copy is made. These include copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: Delete within 180 days after the recordkeeping copy has been produced.

b. Copies used for dissemination, revision or updating that are maintained in addition to the recordkeeping copy.

Disposition: Delete when dissemination, revision, or updating is complete.

15.38.6.1 – Compliance Standards for Pharmacy Accreditation

(Rev. 346, Issued: 06-25-10, Effective: 01-01-11, Implementation: 01-03-11)

The National Supplier Clearinghouse (NSC) shall not require that a pharmacy be accredited as a condition of enrollment before January 1, 2011.

The NSC-MAC shall determine which enrolled suppliers are pharmacies that are not accredited and who will be enrolled for 5 calendar years prior to January 1 of the next calendar year. The NSC-MAC shall then send a notice of revocation by January 10, 2011, to all enrolled pharmacies who are not accredited and who will not be enrolled for 5 calendar years as of January 1, 2011.

The NSC-MAC shall prepare a letter which enables all individually enrolled practice locations of pharmacies who have been enrolled for 5 calendar years prior to January 1, 2011, to attest that they are exempt from the requirement to be accredited because their total durable medical equipment, prosthetics orthotics and supplies (DMEPOS) billings subject to accreditation are less than 5 percent of their total pharmacy sales, as determined based upon the total pharmacy sales of the pharmacy for the previous 3 calendar or fiscal years. The letter shall cite that the attestation requires the signature of the authorized or delegated official of the entity. The authorized and delegated officials are defined in Section 15, of the Medicare Enrollment Application (CMS-855S), and as described in the internet enrollment application version of the Provider Enrollment, Chain and Ownership System (PECOS). Before mailing the letters, the NSC-MAC shall obtain NSC project officer approval of the letter. The mailing shall be in the form of an endorsement letter with an enclosed stamped self addressed envelope. The mailing should be performed between October 1, 2010 and October 31, 2010. For pharmacies with more than one practice location, the letters shall cite the need for each individually enrolled practice location to attest that they are exempt from the accreditation requirements. New locations of enrolled chain pharmacies shall not be considered to have been enrolled for 5 calendar years. Pharmacies that have had a change of ownership in the prior 5 years which resulted in a change in their legal business entity, including a change in their tax identification number (TIN), shall not qualify for an attestation accreditation exemption and therefore shall not be sent the attestation letter.

The NSC-MAC shall review the attestations received from pharmacies. Pharmacies that properly signed the attestation letter shall be given an accreditation status of exempt. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their attestations. The NSC-MAC shall send a notice of revocation by January 10, 2011, to all enrolled pharmacies who were sent an attestation letter and have not properly completed it as of the date of the notice of revocation. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

Between April 1, 2011 and April 30, 2011, the NSC-MAC shall compile a sample listing of at least 10 percent of the pharmacies that have submitted an NSC accepted attestation exempting them from accreditation. The NSC-MAC shall develop a letter to be sent to pharmacies that will be audited to determine if their accreditation exemption attestations are correct. The letter shall request submission of evidence substantiating that the validity of the pharmacy supplier's attestation. At a minimum, requested materials for this evidence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant

periods. The NSC-MAC shall obtain NSC project officer approval of the letter. Within 45 days after project officer approval of the letter the NSC-MAC shall mail a copy of the letter to the random sample of pharmacies which claimed exemption through an attestation. The NSC-MAC shall determine the acceptability of the replies received in response to the audit verification random sample mailing. The NSC shall use DMEPOS billing data for only products and services requiring accreditation to assist in the determination. The NSC shall make attempts to assist and follow-up with pharmacy suppliers that have not submitted or properly completed their audit verifications. The NSC-MAC shall consult with the NSC project officer in cases where they are uncertain as to the acceptability of the supplier's response to the audit request. By June 30, 2011, the NSC-MAC shall send a notice of revocation to all enrolled pharmacies that were sent an audit verification letter who did not submit satisfactory evidence that they were in compliance with the requirements to obtain an accreditation exemption. The notice of revocation shall cite that the revocation is for a lack of required accreditation.

The NSC-MAC shall follow the procedures shown above concerning issuance of attestation letters and audit survey letters for all succeeding years after they have been performed for the first time.

15.17 – Establishing an Effective Date of Medicare Billing Privileges
(Rev.)

15.17.4 – Certified Provider or Supplier Agreement or Approval
(Rev.)

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R372PI	03/25/2011	Effective Date of Certified Provider or Supplier Agreement or Approval	04/25/2011	7232
R371PI	03/23/2011	Implementation of Provider Enrollment Provisions in CMS-6028-FC	03/25/2011	7350
R365PI	01/28/2011	Diabetes Self-Management Training (DSMT)	04/29/2011	7236
R363PI	01/14/2011	Clarification for Part A Contractors Including Audit and Claims Intermediaries Notifying Each Other via E-mail Upon Processing of the Initial Enrollment Application, Change of Information, Voluntary Termination, or Any Other CMS-855 Transaction	02/15/2011	7221
R358PI	10/29/2010	Indian Health Service (IHS) Facilities and Tribal Provider's Use of Internet-based Provider Enrollment, Chain and Ownership System (PECOS)	11/29/2010	7174
R357PI	10/01/2010	Durable Medical Equipment (DME MAC) and the National Supplier Clearinghouse (NSC MAC) Procedures for Third Party Notification of Deceased Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) Supplier Associates	10/04/2010	6714
R356PI	09/24/2010	Manual Redesign	10/26/2010	7083
R355PI	09/17/2010	Eligible Physicians and Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Services for Medicare Beneficiaries	10/18/2010	7097
R354PI	08/27/2010	Manual Redesign	09/28/2010	7016
R353PI	08/27/2010	Notification to State Medicaid Agencies and Child Health Plans of Medicare Terminations for Certified Providers and Suppliers	09/28/2010	7074
R350PI	08/20/2010	Notification to State Medicaid Agencies and Child Health plans of Medicare Revocation	09/21/2010	7017
R347PI	07/15/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15	07/30/2010	6938
R346PI	06/25/2010	Guidance on Implementing Section 3109 of the Patient Protection and Affordable Care	01/03/2011	7021

Rev #	Issue Date	Subject	Impl Date	CR#
		Act (PPACA)		
R344PI	06/18/2010	Chapter 10 Manual Redesign - Initial release of Chapter 15 - Rescinded and replaced by Transmittal 347	07/05/2011	6938

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